

Commission of Inquiry on Hormone Receptor Testing

Volume 1: Investigation and Findings

The Honourable Margaret A. Cameron
Commissioner

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Preface

The Commission of Inquiry on Hormone Receptor Testing was established by Order in Council 2008-300 on July 3, 2007. The authority of the Commission is stated in the *Public Inquiries Act, 2006* and the Terms of Reference contained in the Order establishing the Commission.

This is an investigation into the estrogen and progesterone receptor (ER/PR) tests performed in Newfoundland and Labrador from 1997 to 2005. Though appointed by the Government of Newfoundland and Labrador, the Commission is independent of Government. The Commission is not a court and I am prohibited from expressing any conclusions or making recommendations regarding civil or criminal responsibility of any person or organization. Consequently, no attempt is being made in this report to identify specific reasons for any changes in test results for individual patients.

Those patients or relatives of patients who gave evidence during the hearings were chosen because their stories illustrate the many different ways that the ER/PR problem affected patients.

As one might anticipate, with 93 witnesses, heard over 128 days of testimony, there were many differences in recollections of events. Some of these differences are unimportant to the facts which must be determined to answer the questions raised by the Terms of Reference. The findings I have made are reflected in the story as I have told it. Failure to make specific reference to other versions of the facts should not be taken as failure on my part to consider the testimony of those persons who might have different views or recollections.

As I said in my first public statement about the work of Inquiries:

Public Inquiries are designed to expose certain events to public scrutiny. Usually, a Commission is asked to determine what went wrong in the past and how to avoid such errors in the future.

Hormone Receptor Testing

While in respect of the ER/PR tests performed from 1997 to 2005 this has been a look back, in other respects the matter under review is not yet complete. As the Commission was doing its work and the hearings were being held, the data was changing. This point is illustrated by the “simple” question, “How many patients’ test results were re-tested?” This figure must be kept separate from how many re-tests were done, as a number of patients had more than one block re-tested or, for some reason, were tested a third time. On December 11, 2006, Eastern Health stated that 939 patients were re-tested at Mount Sinai. A review of those numbers by the Newfoundland and Labrador Centre for Health Information revealed that as of March 11, 2008, 1013 patients had been re-tested. The discrepancy is partially explained by patients who were identified after the publication of the number of 939 or by the re-testing of known deceased patients who had not been re-tested before.

As well, during the hearings, further decisions were being made by Eastern Health regarding communication with patients or their families (e.g., the decision by the acting CEO to send an apology letter). Eastern Health also plans to communicate with the public by having their story written. Sometimes witnesses used the hearings themselves to communicate with the patients or the public (e.g., statements of apology made by Ms. Dawe, chair of the Board of Trustees of Eastern Health, and Mr. Williams, Premier of Newfoundland and Labrador). Unless otherwise stated, the findings of fact contained in this report are based on the testimony given and the exhibits received up to the completion of the hearings.

The report is in three volumes: Volume 1 contains my investigation and findings related to the events, and my responses to the Terms of Reference. Volume 2 contains the papers commissioned by the Inquiry and discussed at a public symposium sponsored by the Commission in the spring of 2008. I believed these papers constitute a valuable contribution to the work of the Commission. The report appendices can be found at Volume 3. The report is also available on compact disc and, for a limited period, on the Commission’s website.

Early in the process I decided that I wanted to have the hearings web cast. I was very conscious of the fact that while Eastern Health might be at the centre of the Inquiry, there are three other regional health authorities and affected patients came from every part of the Province. I concluded that the internet could provide an effective method of communication for patients living both in and outside the province who were not in a position to attend in person. Just before the hearings began Roger's TV, channel 9, asked to broadcast the proceedings and I agreed, in the belief that this would be another method of allowing interested viewers to learn directly from those involved and draw their own conclusions. In addition, television newscasts often carried excerpts from the testimony. There were members of the media who regularly covered the hearings; they were courteous of the Commission's process.

I discovered that there were advantages and disadvantages to these efforts to provide as much public access as possible, some of which I had not anticipated. First, two of our witnesses contacted us because of what they saw on a newscast. Second, it lengthened the hearings. While observers in our hearing room could see on a large screen the exhibits to which a witness was being referred, those watching via television or internet could not. Therefore, to make the testimony meaningful for those members of the public watching, when questioning witnesses commission counsel had to read much more of the content of documents than would otherwise have been necessary. Third, I understood and anticipated that the broadcasting of the testimony might add to the stress and nervousness which most witnesses could be expected to feel, but I did not anticipate the nature of the preparation which would be involved in dealing with an appearance at the Inquiry.

I acknowledge my gratitude to Justice Bellamy, Justice O'Connor and Justice Linden for having included in their reports volumes relating to process. I found both volumes to be extremely helpful, particularly in the early stages. That work having been done so well, it would be superfluous to produce such a volume in this report. I wish, however, to make some observations which I hope will be of assistance to future commissions.

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I underestimated the time which would be required for start up. Even with the assistance of officials from government departments it took two months to find accommodation, acquire the necessary furniture and, most important, find the staff, most of whom had commitments to other positions when they agreed to come to work for the Commission.

The operation of the Commission is arms-length from government so an independent information technology infrastructure was required. Even with the assistance of the Office of the Chief Information Officer for the province, we were nearing the third month of the Commission's term before our information technology infrastructure was operational and a database had been established to manage the voluminous documentation to be received by the Commission.

While for the most part the Commission enjoyed a cooperative relationship with the parties with standing, the Commission's ability to process documentation and the ability of the Commission to do its work in the most efficient and effective manner was at times compromised by the late production of documents. There were times when documents relevant to a particular witness's testimony were produced only after that witness had testified or so close to the witness's testimony that Commission staff were unable to meet the time frames set by the Commission's Rules of Procedure and Practice for disclosure of documents to Parties.

This Inquiry has been an open and participatory process; it has attempted to provide an understanding of what went wrong with the ER/PR testing performed from 1997 to 2005 in the Newfoundland and Labrador health system. It is my hope that those affected by these events can feel that their concerns have been heard.

Acknowledgements

I thank Chief Justice Clyde K. Wells for his encouragement and support when I concluded that I wanted to take on the work of the Commission, and my colleagues at the Supreme Court of Newfoundland, Court of Appeal who, with good humour, took on my share of the work at the Court, as it has turned out, for a much longer period of time than we anticipated.

I am indebted to Madam Justice Denise E. Bellamy, Commissioner, Toronto Computer Leasing Inquiry, Toronto External Contracts Inquiry; Mr. Justice Sidney B. Linden, Commissioner, Ipperwash Inquiry; and Mr. Justice Dennis O'Connor, Commissioner, Walkerton Commission of Inquiry. Sections of their reports included detailed descriptions of the inquiry process, which became indispensable guides for me and other members of the team. Justice Bellamy was also generous with her time, when I needed advice. Ms. Linda Rothstein, Lead Commission Counsel for the Inquiry into Pediatric Forensic Pathology in Ontario, gave us the benefit of their experience. Mr. David Henderson of Ontario, who has extensive experience with public inquiries, greatly aided us with his wisdom and advice. I am also grateful for the assistance of W.A. Derry Millar, my old classmate and friend, lead counsel for the Ipperwash Inquiry. As he has since we first met at Dalhousie University, Derry responded promptly when I asked for his counsel.

The Commission has had the benefit of the assistance of a number of persons and groups who facilitated the smooth running of the hearings: Discoveries Unlimited provided transcripts of our hearings and Eastern Audio Limited our audio-visual services.

The work of the Commission of Inquiry has demanded the impossible from our staff. They have always risen to the occasion. I am very grateful to them all.

The first person to join the team was Virginia Connors, the Chief Administrative officer of the Commission. She demonstrates, every day,

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the organizational skills of a general and a knowledge of information management that is truly impressive. Virginia has been supported by our small but dedicated team, some of whom have been with us for the full period of time, some of whom came for shorter periods: Rhonda Guay, Grace Evans, Diane Blackmore, Dorothy King, and Ian Gosse. During the hearings, security services were provided by Leonard Thorne and Lesley Grace. Theresa Heffernan is our Chief Financial Officer and I greatly appreciate her guidance and oversight of the Commission's budget. Elaine Clarke has served as my executive secretary and, during the hearings, as the registrar. Her ability to produce nearly instantaneously the exhibits required from the database greatly facilitated the smooth operation of the hearings. She is a cheerful, tireless and proficient worker. I have enjoyed working with her. Claire Wilkshire, PhD, has been our editor. Having an editor is a luxury I have enjoyed. I also wish to thank Dr. David Dabbs for reviewing a draft of the part of the report which deals with science.

As to the legal team, Bernard Coffey, QC, and Sandy Chaytor, QC, have been co-counsel. It has been truly a pleasure to work with them. Under what were at times very trying circumstances, they demonstrated that they are principled, dedicated professionals. Their abilities to focus and to work long hours have amazed me over and over again. I have also been fortunate to have had the assistance of Timothy Caulfield, LL.M., as the Director of Research. He was indispensable in the organization of the symposium held by the Commission on April 23-24, 2008. I am very appreciative of the efforts of those who participated in the symposium and prepared papers. Volume 2 of this report contains those papers. I recommend them. Mandy Woodland, LL.B., has been my legal research assistant. With Mandy I had the advantage of having someone in-house who had familiarity with a laboratory, an interest in health law and a capacity for juggling many tasks at the same time. The legal team was also assisted, from time to time, by Laurie Jones, LL.B., and Angela Blagdon, LL.B.

I wish to acknowledge and thank the spouses and families of my team for their continued support and understanding.

I also want to thank our witnesses. Some were independent witnesses; others were intimately involved with the ER/PR matter. I know that it was stressful for many of them. I particularly wish to thank those patients and the spouses of deceased patients who were prepared to tell their personal stories. They did so with incredible courage and grace.

I take this opportunity to recognize the professionalism of counsel for the parties with standing and to thank them for their respectful participation in the process. I wish also to thank those members of the public who made submissions to the Commission during Part II of the Inquiry.

Finally, on a personal note, thank you to Judy, Joan, and Harry who so often stepped in to do what needed to be done when I was not there, and to Bill who allowed me to ruminate when I needed to. Over the years, my mother, Isabelle Kirby Cameron, RN, and many of my cousins who chose the same career path, at family gatherings, would debate health care issues. Their yard stick was always - what is the impact on patient care? It is my hope that they, and others, will see this document as a contribution to improving patient care in Newfoundland and Labrador.

Chapter One

Peggy Deane

Peggy Deane

She wanted to live life to the fullest

In the summer of 2002, Margaret (Peggy) Deane, RN, was diagnosed with infiltrating lobular cancer of the right breast with metastasis to the liver. She was then 43 years old, married, with three young children. By 2003, metastasis to the spine was confirmed. While there were periods when she seemed to be making progress, those periods of reprieve from the relentless march of the disease did not last long. By the spring of 2005, Ms. Deane had tried all recommended treatments. She had also consulted an oncologist in Toronto, who agreed with the treatment choices that had been made in St. John's, Newfoundland and Labrador.

Ms. Deane's husband described her as having wanted to "live life to the fullest" while she could. It was Peggy who, in the spring of 2005, suggested to her husband that they take a trip to New York. By coincidence, at the hotel where they stayed there was a conference on cancer treatment. While in an elevator, Robert Deane noticed the name tag of a fellow passenger. The tag identified the wearer as being associated with the Sloan-Kettering Institute. Robert Deane, himself a physician, knew the excellent reputation of Memorial Sloan-Kettering Cancer Center. He struck up a conversation with the person wearing the tag and asked whether there was anything new on the horizon or something experimental in which his wife might participate. He was encouraged to learn that there were a couple of ongoing clinical trials. Perhaps there might be a chance if Peggy became part of a trial for some new treatment.

On returning to St. John's, he and Peggy raised with her oncologist the idea of participation in a trial of a new treatment. The oncologist, Dr. Kara Laing, was not optimistic, but she agreed to make inquiries. On April 9, 2005, Dr. Laing emailed Dr. Clifford Hudis, a breast oncologist at Memorial Sloan-Kettering Cancer Center, inquiring about the possibilities. In her email, Dr. Laing briefly explained the medical history of her patient. Dr. Hudis promptly responded: "ER and PR NEGATIVE

invasive lobular? Very rare, to say the least. If you are sure it is Invasive lobular I would repeat the ER/PR.” He added that they did not have any clinical trial option at that time. Dr. Laing replied: “ER was negative and PR was weakly positive in < 10% which we consider negative. Can get it rechecked.” Dr. Hudis answered: “I have never seen an ER/PR negative invasive lobular.”

As it happened, Ms. Deane was in hospital in St. John’s when the ER/PR re-testing occurred. Both the estrogen and progesterone receptor status changed to positive. Before she was discharged from hospital on April 20, 2005,¹ Ms. Deane’s treatment had been altered to include the drug tamoxifen. This change was a direct result of the change in the hormone receptor status of her breast tumour. Anti-hormonal drug treatment had in 2002 been rejected as an option because of Ms. Deane’s negative hormone receptor result. By July, 2005 another drug, Femara, was substituted for tamoxifen.

On August 5, 2005, Peggy Deane died.

Ms. Deane’s case became known within Eastern Health² as the “index case.” Within that institution, it was considered the case that first identified problems with ER and PR testing in Newfoundland and Labrador. In 2005 and 2006, re-tests were completed on hundreds of other cases that had, between 1997 and 2005, been found to be ER negative. It was the “high rate of conversion” on re-testing and the way information about the re-tests was communicated to the patients involved that gave rise to this Inquiry.³

The events of 2005 did not start there. They began much earlier.

¹ Peggy Deane began taking tamoxifen before April 20, 2005. The addendum to her chart to reflect this change in hormone receptor status was not made until May 31, 2005.

² Eastern Regional Integrated Health Authority.

³ Commission of Inquiry on Hormone Receptor Testing Order, NLR 72/07, July 03/07.

Chapter Two

Organizational Structures

Organizational Structures

Over the last three decades there has been a dramatic decrease in the number of separate organizations and facilities providing health care in Newfoundland and Labrador. For the purpose of this Inquiry, however, it is necessary to refer only to the fact that in the mid-1990s, numerous boards¹ providing various levels of health care in Newfoundland and Labrador were combined into 14. The Health Care Corporation of St. John's (Healthcare) was one of the 14 created during that time. It came into existence on April 1, 1995. It ceased to exist when Eastern Health was created 10 years later. On April 1, 2005, the 14 health care boards and other community agencies became part of four regional health authorities: the Eastern Regional Integrated Health Authority, the Central Regional Integrated Health Authority, the Western Regional Integrated Health Authority, and the Labrador-Grenfell Regional Integrated Health Authority.²

The primary impact of the creation of Healthcare was the uniting under one board of a number of acute care institutions in St. John's. These were: the Waterford Hospital, St. Clare's Mercy Hospital, the Salvation Army Grace General Hospital, the General Hospital,³ and the Janeway Child Health Centre (Janeway).⁴ All these hospitals had laboratories; all but the Waterford Hospital included pathology services⁵ in their laboratory services.

¹ Ms. Joan Dawe, Chair of the Board of Trustees of Eastern Health, stated it had been 54 boards; Mr. Tilley, CEO of Eastern Health, thought that it was in excess of 60 boards.

² A map showing the geographic locations of these regional health authorities can be found in Volume 3, Appendix 24, of this report.

³ The General Hospital is located at the Health Sciences Centre. For the purpose of this report, "Health Sciences" and "General Hospital" are used interchangeably.

⁴ Other facilities that became part of Healthcare group were the Children's Rehabilitation Centre, the Dr. Walter Templeman Health Centre (Bell Island), and the Leonard A. Miller Centre.

⁵ If a hospital provides a full range of services, these would be expected to include biochemistry, cytology, hematology, microbiology, and pathology.

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While the ER/PR problem was discovered on Eastern Health's watch, it was created on Healthcare's. Some organizational decisions made by Healthcare are relevant to the mandate of this Commission. Initially, the organizational structure of Healthcare was based on the employee's position, rather than the sector of the organization in which the employee worked. So, for example, nurses reported through a nursing structure to a director of nurses, regardless of which unit or area of the institution they worked in.

Healthcare soon shifted to a program management model of organization, which was based on the types of service being provided. With the program management model, employees reported not according to their function but according to the department in which they worked. All staff in a given department were to report through that department, regardless of whether they were, for example, nurses, technicians, or other employees.

There was an exception within the reporting structure. Physicians did not report through the same department managers or directors as other members of the team. Rather, for each department or program, there were two leaders: a clinical chief and a program director. The physicians reported through the clinical chief. Everyone else on the team reported through the program director.

Mr. George Tilley, CEO of Healthcare and, later, of Eastern Health, saw this shift to a program management model of organization as part of a movement toward a more patient-focused system that would provide the additional benefit of a more interdisciplinary approach to the delivery of health services. Eastern Health generally continues to use the program management model.

Organization of the Laboratory Medicine Program

With the creation of Healthcare, all laboratories in the organization fell under one administrative structure. One program director was appointed for all the laboratories within Healthcare. Reporting to the program director were divisional managers for each of the laboratory programs (biochemistry, haematology, and so on), though the divisions

do not appear to have been always strict. For example, when Mr. Terry Gulliver became a divisional manager for pathology, he also managed immunology, and genetics was later added to his responsibilities. For pathology, there were two divisional managers: Mr. Gulliver for the Janeway Hospital and the General Hospital (Health Sciences) and Mr. John Murphy for St. Clare's Hospital and, for a time, the Grace Hospital. When the program management model was first introduced at Healthcare, the program director for laboratory medicine reported to the Senior Vice-President for Corporate Affairs, who reported to the CEO.

In keeping with the program management model, there was a clinical chief of laboratory medicine who was a pathologist. He and the program director formed the leadership team. There might be one additional member, if the Faculty of Medicine of Memorial University had appointed a discipline chair for laboratory medicine. Often, however, the clinical chief might also occupy the position of discipline chair. For pathology there were also site chiefs, who were pathologists at each laboratory where anatomic pathology services were offered. A site chief's primary duty was to be a resource person for the technical staff and a conduit for communication between pathologists and technologists. Site chiefs reported to the clinical chief. The first clinical chief appointed under the new organizational structure was Dr. David Haegert, a pathologist, who was also the discipline chair. He reported to the Vice President, Medical Services, who reported to the CEO.

Later, the structure was changed so that the program director also reported to the Vice President, Medical Services, of Healthcare and, when Eastern Health was formed, to the Vice President, Quality, Diagnostic and Medical Services.

Before Healthcare was formed, it was planned that the Grace Hospital would be closed. Further, the Janeway was to move to a new building adjacent to the General Hospital. Laboratory physicians and technologists who worked at the Grace Hospital⁶ were moved to either the General Hospital or St. Clare's Hospital. When the Janeway opened on the new site in June 2001, some laboratory functions continued to be

⁶ The Grace Hospital closed in September 2000.

performed within the Janeway itself, while others were moved to the General Hospital. The disruption in the working lives of technologists and physicians, particularly for those who had worked at the Grace Hospital, was great. That experience was to colour the attitude of some pathologists when it was later proposed that all pathologists operate out of the General Hospital.

The Beginnings of Healthcare and Eastern Health

A number of the witnesses who had experienced the beginnings of Healthcare and those of Eastern Health contrasted the two. In particular, the inaugural management team of Healthcare had one year before the creation of Healthcare to develop a strategic plan for the new organization. In contrast, Eastern Health's CEO, Mr. Tilley, was appointed only a few months before April 1, 2005. He had been CEO of Healthcare immediately before Eastern Health was formed, but Eastern Health was the result of the amalgamation of seven organizations, and the number of employees of Eastern Health was nearly double that of Healthcare. Another difference between the formation of Healthcare and that of Eastern Health was that, while Healthcare essentially united organizations providing very similar services, Eastern Health incorporated into its structure community-based services such as child protection and long-term care facilities, which were providing services of very different, albeit related, kinds. Further, Eastern Health provides services throughout a larger region and manages facilities and services in rural areas. Its facilities include hospitals in Clarendville, Carbonear, and Burin, and offices and long-term care facilities in many locations.

The Newfoundland Cancer Treatment and Research Foundation (NCTRF) was also brought within the Eastern Health group, though the final legal step of repealing the applicable legislation did not occur until 2008. When the Cancer Care Program, which had been administered by the NCTRF, was brought under Eastern Health, cancer care for the whole of the Province not only came under the Board of Trustees of Eastern Health but also adopted the same management structure as that which existed in Eastern Health's hospitals. Dr. Kara Laing, a medical oncologist, became the clinical chief, Cancer Care Program, and Ms. Sharon Smith the program director, Cancer Care Program. More recently,

Dr. David Saltman, a discipline chair in oncology at Memorial University, was added to the leadership team.

Very few positions other than CEO were filled before Eastern Health came into existence and the ER/PR problem emerged. Consequently, most of those who ultimately became involved in the ER/PR issue⁷ were applying for positions within the newly created Eastern Health at the same time as they were performing their jobs and juggling the ER/PR problem. However, comparing the positions held by these people when they were employed by Healthcare with those to which they were appointed in Eastern Health, one finds the following: Mr. Tilley was the CEO of both Eastern Health and, immediately prior to its demise, Healthcare; Dr. Robert Williams, Vice President of Medical Services, held essentially the same position in both organizations and the laboratory medicine program reported to him until his retirement in September 2006, when he was replaced by Dr. Oscar Howell. Ms. Susan Bonnell, Director of Strategic Communications, had the same position in both organizations. Ms. Heather Predham, Risk Management Consultant, had responsibilities for quality in both organizations. Dr. Donald Cook was clinical chief of laboratory medicine from October 11, 2002, to March 10, 2006, and site chief at St. Clare's from November 1, 1996, to the present. These appointments span both organizations, though not the entire period under consideration by the Commission. Dr. Kara Laing began practice as a medical oncologist at the Newfoundland Cancer Treatment and Research Foundation in 1999. After the creation of Eastern Health, she took on additional duties as clinical chief, Cancer Care Program. The positions of Dr. Al Felix, surgeon, Dr. Alan Kwan, surgeon, and Dr. Joy McCarthy, oncologist, were unchanged.

The people dealing with the ER/PR problem held essentially the same positions within Eastern Health as they had when they worked for Healthcare. Further, many individuals in the other organizations involved in the ER/PR problem were well known to those within Eastern Health. For example, Mr. John Abbott, the Deputy Minister of Health and Community Services, had been the chairperson of the Board of Trustees of Healthcare from 2002 to 2004. Ms. Pam Elliott, Director of Quality and

⁷ The exceptions were Mr. Tilley and Ms. Bonnell.

Risk Management at Eastern Health since October 2005, had been an Assistant Deputy Minister (Board Services) with the Department of Health and Community Services from 1997 to 1999. Dr. Williams had had a long career within the Department of Health, including a period as Deputy Minister of that Department from 1989 to 1998, and then joined the Healthcare Corporation in May 1998.

Hay Group Report

In 2001 the Government of Newfoundland and Labrador had commissioned an operational review of Healthcare by the Hay Group. The mandate of the Hay Group was to identify ways of reducing costs, with the goal of having Healthcare operate within its budget. Historically, there had been a number of years of deficits. Eight of the recommendations of the Hay Group related to laboratory services. These included reducing the number of management positions and establishing productivity targets. Another recommendation was that “the director of laboratory services should reduce staffing in pathology by 2.0 FTE’s in Cytology and 1.0 FTE in histopathology and make investments to train 3 pathology assistants.” In its response, Healthcare stated that it did not support the recommendation. It added: “pathology assistants are not readily available in this province as there is no local training program for pathology assistants. Technologist IIs have been cross-trained to do some of this work.” The question of the use of pathology assistants had been discussed on a number of occasions over the years. It would be raised again in the context of the ER/PR problem. Fiscal problems had been a large part of the history of the boards that preceded Healthcare and of Healthcare itself. Financial management was a preoccupation.

Dr. Diponkar Banerjee, the Provincial Program Leader, Cancer Pathology for the British Columbia Cancer Agency and Director of Laboratories at the Vancouver Cancer Centre, was retained as an expert consultant by Eastern Health. He visited St. John’s in September 2005 and provided a report dated October 17, 2005, to Eastern Health.⁸ In that report he noted the following regarding the organization of the pathology laboratory:

⁸ Dr. Diponkar Banerjee’s report is discussed at length throughout this document.

Disconnect between Laboratory Program Director, Division Manager, Clinical Site Chief, and Laboratory Director in decision making. The organizational charts indicate a complete separation of reporting structures into technical and clinical streams with no matrixed cross-reporting between technical and medical leadership. This leads to frustration and resentment on both sides, lack of communication, lack of accountability, and lack of buy-in. The Division Manager and Program Director appear enthusiastic and keen on modernizing the laboratory, but their efforts have not been appreciated by the pathologists and workflow changes have not been mapped out and implemented (e.g., Sakura Express implementation has failed due to lack of planning of workflow changes). Superior outcomes could be achieved by ensuring better linkages between technical, managerial and medical leadership.⁹

Dr. Banerjee, in his testimony before the Inquiry, addressed the management structure within the laboratories. He acknowledged that the system in operation at Healthcare, and at the time of his visit to Eastern Health in 2005, is quite common in other jurisdictions. Within Eastern Health in 2005, and for many years before that within Healthcare, differences of opinion among the members of the leadership team had to be resolved by Dr. Williams, the Vice-President responsible for the laboratory medicine program. Dr. Banerjee's opinion was that this effectively made Dr. Williams, who was not a pathologist, the laboratory director. Dr. Banerjee opined that the structure should permit the final arbiter of differences among the leadership team to be someone within the laboratory medicine program and that the person should be a pathologist. While he acknowledged that the program management structure could work well where there is a level of co-operation among the members of the leadership team, Dr. Banerjee felt that there should be a structure that does not rely upon the willingness of individuals to co-operate for decision making. He put it this way:

So, if you have ... a dual management model where the lab director and the program or lab manager get along very well, then it works. But if they don't get along very well, the structure doesn't help the situation because when things go wrong, nobody is actually accountable because they'll say, well, it wasn't my problem; it was that person's problem.¹⁰

⁹ Exhibit P-0046, p. 5.

¹⁰ Transcript of testimony, Dr. Diponkar Banerjee, July 30, 2008, pp. 308-310.

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Whatever one's view of the program management model, the weakness of its application in the laboratory setting, as described by Dr. Banerjee, manifested itself when the ER/PR problem arose. Examples of this will be seen throughout this report.

Subsequently, Eastern Health changed the management structure within the Laboratory Medicine Program to reflect Dr. Banerjee's recommendations. Dr. Nebojsa Denic became Clinical Chief of Laboratory Medicine. The program director now reports to the Clinical Chief of Laboratory Medicine except in respect of certain administrative and budget issues. For those matters, the program director continues to report to the Vice President, Medical Services and Diagnostics. I conclude from the evidence of Dr. Denic and Dr. Howell that the question of the proper management structure for laboratory medicine has not yet been finally answered. They continue to examine other options.

Chapter Three

Science and Technology

Science and Technology

The removal of the tumour is, for most breast cancer patients, just the first step. There may be further treatments, as there were for Ms. Deane, such as chemotherapy and radiation therapy. The decisions about such therapy are made by the patient in consultation with his or her physicians.

A pathology report is a factor considered by the treating physician, usually an oncologist, in providing advice to his or her patient. A pathologist examines the tumour removed from the patient and gives an opinion as to whether the tumour is carcinoma and, if so, the type of breast cancer involved, such as whether the tumour is invasive or in situ (not invasive), ductal, or lobular.¹ The pathology report will generally also state the estrogen receptor (ER) and progesterone receptor (PR) status of the cancer cells. These receptors are found in about 75%² of all breast cancers. A report as to the presence or absence of these receptors assists the oncologist in forming an opinion about whether anti-hormonal therapy could be effective for the patient. Tamoxifen, a drug taken in pill form, is given to inhibit the effect of estrogen on cancer cells and consequently discourage the growth of the tumour. Aromatase inhibitors are also sometimes used for that purpose. For Ms. Deane tamoxifen represented another class of treatment she could try.

The Role of Pathology

[Pathology] involves the investigation of the causes (*etiology*) of disease as well as the underlying mechanisms (*pathogenesis*) that result in the presenting signs and symptoms of the patient. Pathologists use a variety of molecular, microbiologic, and immunologic techniques to understand the biochemical, structural, and functional changes that occur in cells, tissues, and organs. To render diagnoses and guide therapy, pathologists identify changes in the gross

¹ There are other types of tumours, but these are more commonly found.

² Dr. Frances O'Malley advised that in some studies it is said to be up to 80% (June 23 2008, p. 142).

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or microscopic appearance (*morphology*) of cells and tissues, and biochemical alterations in body fluids...³

The objective of clinical pathology is to serve patients by providing important diagnostic information along the way to treatment and cure or control. A clinical pathology laboratory processes patients' tissue samples for the purpose of enabling the diagnosis of disease and to give clinicians information relevant to their treatment decisions.⁴

The Evolution of ER and PR Testing

In 1889 it was suggested that endocrine ablation⁵ could be important in the treatment of breast cancer. In 1896 Dr. Beatson performed the first operation to remove the ovaries of a patient with inoperable breast cancer, and he later reported that "eight months after the operation the disease in this patient had disappeared."⁶ The first controlled study of endocrine ablation occurred four years later and involved 54 patients with advanced breast cancer. Dr. Boyd removed the patients' ovaries, and 35 percent of the patients went into complete remission. A hiatus in any further treatment improvements lasted several decades.⁷ The question debated in medical circles during that period focused largely on whether removal of the ovaries of patients with breast cancer should be prophylactic or therapeutic, based on how advanced the disease was. Until 1960, information on this aspect of treatment for breast cancer was controversial in the medical literature. In 1960 Jensen and Jacobsen demonstrated that radioisotopic and radioactive estrogen accumulates in target tissues in the body in the pituitary gland, vagina, and uterus, and that radioisotopes were found in the cytoplasm and nucleus of these targeted cells. This suggested that ablation of the pituitary gland (which controls the ovary) or adrenal gland (which is also controlled by the pituitary) might be a treatment to eliminate these

³ Kumar, Vinay, et al., *Robbins Basic Pathology*, 8th ed. (Philadelphia: Saunders Elsevier, 2007).

⁴ Submission of Eastern Health, para. 51.

⁵ Ablation - "1. separation or detachment; extirpation; eradication. 2. removal or destruction of a part, especially by cutting" (*Dorland's*).

⁶ Transcript of testimony, Dr. David Dabbs, September 15, 2008, p. 117; Exhibit P-2621.

⁷ Transcript of testimony, Dr. David Dabbs, September 15, 2008, pp. 117-118; Exhibit P-2621.

sources of estrogen in the body. Between 1965 and 1970, a number of articles were published on the subject, including a paper in 1965 that demonstrated for the first time that breast tumours can take up estrogen and bind to it. Sentinel papers published during this time demonstrated that breast cancers do, in fact, take up estrogen. McGuire in the late 1960s and 1970s demonstrated a method of showing that the estrogen that binds in breast tumours can be measured. This test became known as the dextran-coated charcoal (DCC) ligand-binding method.⁸

The ligand-binding method, or biochemical assay, became the most common method of testing for the presence of estrogen and progesterone hormone receptors in a tumour. After its removal from a patient, tissue was homogenized⁹ and the cytosol, or fluid portion of the cytoplasm (the organized complex of inorganic and organic substances external to the nuclear membrane of a cell and including the cytosol and membrane-bound organelles) is fractionated through the sucrose density. Those fractions are isolated and exposed to radio-labelled estrogen; the radioactive estrogen binds to the estrogen receptors present in the cytoplasm of the cells. This mixture is then exposed to a slurry¹⁰ of dextran-coated charcoal, which removes the unbound estrogen in the mixture, and the radioactive-bound receptors are counted in a scintillation counter¹¹ to measure the amount of radioactivity present. The final result is expressed in femtomoles of estrogen receptor protein per milligram of cytosol protein.

The ligand-binding method had a number of drawbacks. It required relatively large amounts of fresh tissue, and required the tissue

⁸ Transcript of testimony, Dr. David Dabbs, September 15, 2008, p. 118 and p. 119; Exhibit P-2621.

⁹ Homogenize - "to render homogeneous, or of uniform quality or consistency throughout" (*Dorland's*).

¹⁰ Slurry - "a watery mixture of insoluble matter" (*Medline dictionary*).

¹¹ Scintillation counter - "an instrument for indicating the emission of ionizing particles, making possible the determination of the concentration of radioactive isotopes in the body or other substance; the radiation is absorbed by a specific type of crystal or liquid that subsequently emits minute flashes of light, which are detected and amplified by a photomultiplier tube and counted if they fall within a preset window of energies characteristic of the radioisotope in question" (*Dorland's*).

Hormone Receptor Testing

to be frozen immediately upon its removal from the patient. This created problems with scheduling and would have been difficult in any facility, particularly if there were not sufficient staff to attend the operating room to collect and freeze the tissue any time such a procedure was being performed. It also complicated the transportation of specimens. As well, this method required the use of radioactive material and carcinogenic¹² reagents, which require extensive regulation and training of staff, and more expensive laboratory equipment of the type more commonly found in research laboratories. The other main concern with the ligand-binding method was the issue of samples being “blind,” in that the tissue being analyzed could sometimes comprise tumour tissue and normal tissue, or even no tumour tissue at all. This meant that results could reflect as little as 10 or 20 percent tumour tissue in a sample, and thus there existed the potential for many false negative results.¹³

Immunohistochemistry (IHC), a process that uses antibodies¹⁴ to provide diagnoses in pathology, was initially developed in 1974. In 1978, a sentinel paper entitled “The Immunofluorescent Detection of Estrogen Receptors in Breast Cancer”¹⁵ was published. This paper was the first to demonstrate the method of detecting estrogen receptors using a polymer labelled with fluorescein,¹⁶ which could be seen under a special

¹² Carcinogen – “any cancer-producing substance” (*Dorland’s*).

¹³ Transcript of testimony, Dr. David Dabbs, September 15, 2008, pp. 124-125; Exhibit P-2621.

¹⁴ Antibody – “an immunoglobulin molecule that has a specific amino acid sequence by virtue of which it interacts only with the antigen that induced its synthesis in cells of the lymphoid series (especially plasma cells), or with antigen closely related to it. Antibodies are classified in groups named according to their mode of action, such as agglutinins, bacteriolysins, hemolysins, opsonins, precipitins, and others” (*Dorland’s*).

¹⁵ Pertschuck et al., *Cancer* 1978: 41: 907-11.

¹⁶ Fluorescein – “a yellow or red crystalline dye C₂₀H₁₂O₅ with a bright yellow-green fluorescence in alkaline solution that is used as the sodium salt to aid in diagnosis (as of lesions and foreign bodies in the cornea or of brain tumors)”; fluorescence – “luminescence that is caused by the absorption of radiation at one wavelength followed by nearly immediate reradiation usually at a different wavelength and that ceases almost immediately when the incident radiation stops; also : the radiation emitted”; luminescence – “the emission of light” (*Medline Dictionary*).

fluorescence microscope.¹⁷ The polymer would bind the estrogen receptor in the cell, and one could see where it bound by looking at the cells under a fluorescence microscope. The study found a ninety percent correlation with the dextran-coated ligand-binding method, and this new technique eliminated many of the concerns with the ligand-binding method. The paper noted that tumours with less than ten percent positive cells were “negative” by the ligand-binding method, and those with eleven to twenty percent positive were “borderline” by the ligand-binding method. As Dr. David Dabbs testified, this is one of the first times “ten percent” is mentioned in the literature, a figure that permeated the ER testing literature throughout the 1980s and 1990s.¹⁸ Many papers followed the first, and the evolution of immunofluorescent staining and immunohistochemistry took shape. The method evolved from using fluorescence-labelled antibodies¹⁹ to visualize proteins in frozen tissue to identifying proteins in formalin-fixed, paraffin-embedded tissue that could be viewed by light microscopy.²⁰ The IHC process was in widespread use internationally in the field of histology²¹ by the mid-1980s.²²

In 1985, a paper by Shimada et al.²³ showed that immunocytochemical staining of ER in paraffin sections using

¹⁷ Fluorescence microscopy - “microscopy of natural fluorescent materials or of specimens stained with fluorochromes, which emit light when exposed to blue light or ultraviolet radiation” (*Dorland’s*).

¹⁸ Transcript of testimony, Dr. David Dabbs, September 15, 2008, pp. 126-127; Exhibit P-2621.

¹⁹ Antibody - an immunoglobulin molecule that has a specific amino acid sequence by virtue of which it interacts only with the antigen that induced its synthesis in cells of the lymphoid series, or with any antigen closely related to it. Antibodies are classified in groups named according to their mode of action (Abbreviated as Ab.) (*Dorland’s*).

²⁰ Transcript of testimony, Dr. Diponkar Banerjee, July 30, 2008, pp. 10-11; Dr. Banerjee testified that frozen section morphology was more difficult to interpret than formalin-fixed tissue morphology (p. 23).

²¹ Histology - “that department of anatomy which deals with the minute structure, composition, and function of the tissues; called also microscopic anatomy. Normal histology is the histology of normal tissues; pathologic histology is the histology of diseased tissues, also called histopathology” (*Dorland’s*).

²² Taylor, C. R. “The Total Test Approach to Standardization in Immunohistochemistry” *Arch Pathol Lab Med* 2000 July; 124(7): 945-51.

²³ *Proc Natl Acad Sci* 1985; 82: 483-7.

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monoclonal antibodies was comparable to using frozen sections. This paper was also one of the first to compare the immunoperoxidase method with the Avidin-Biotin method for immunohistology. In the same year, another paper on ER analysis was published, the first to attempt to quantitate estrogen receptor results by immunohistochemistry and compare them with results achieved through previous methods and with patient outcome. The paper proposed the use of the “H Score,” which is still used today in various institutions. The score is the product of the percentage proportion of cells exhibiting nuclear staining, multiplied by the intensity of the staining (using a scale of 0 to 4). The resulting number helps the oncologist or other treating physician to determine what course of treatment should be recommended to a patient.²⁴

The purpose of creating H scores, or other comparable numbers (such as an Allred score)²⁵ that reflect or relate to ER and PR positivity or negativity is to assist clinicians in giving patients advice as to treatment decisions. If anti-hormonal therapy is an option for a patient, it is important to know which patients are more likely to benefit from it, since some anti-hormonal treatment can have potentially serious side effects.²⁶

In 1989 Berger et al. introduced the use of an antibody to progesterone receptors - this was the first method that allowed for routine analysis of progesterone receptors. Progesterone receptor analysis was not routinely performed using the ligand-binding method because it required so much tissue. The introduction of the PR antibody was an important advance for immunohistology.²⁷

During the 1980s, methods for testing for ER continued to evolve, and in 1990 it was confirmed that the ligand-binding method “was not

²⁴ Transcript of testimony, Dr. David Dabbs, September 15, 2008, pp. 131-134; Exhibit P-2621.

²⁵ Allred score to be discussed later in this chapter.

²⁶ Transcript of testimony, Dr. David Dabbs, September 15, 2008, pp. 136-137; Exhibit P-2621.

²⁷ Transcript of testimony, Dr. David Dabbs, September 15, 2008, p. 135; Exhibit P-2621.

necessarily the gold standard that everyone had previously thought.”²⁸ In 1994, papers by Eseban et al. and Pertschuk et al. called for standardization of the IHC test method, recognizing that IHC was the method of choice for determining hormone receptor status of tumours for many reasons, including cost-effectiveness, reproducibility, and outcomes demonstrably as good as or better than those of previous methods.²⁹

The Reasons for Determining ER/PR Status

Anti-hormonal drugs bind to estrogen receptors in a manner similar to the binding of the estrogen molecule. While the binding of estrogen to its receptor results in the receptor’s changing shape and binding to co-activators, binding of an anti-hormonal drug such as tamoxifen (one of a class of drugs known collectively as selective estrogen receptor modulators) to the receptor does not result in the receptor changing shape, and therefore the tamoxifen-estrogen receptor complex cannot bind to co-activators. These co-activators are proteins that initiate a series of events leading to the activation of genes that lead to tumour cell proliferation. Preventing or inhibiting circulating estrogen from stimulating cancer cells is the main action of anti-hormonal therapy.³⁰ While knowledge about this relationship between breast cancer and estrogen is not new,³¹ drug treatments to take advantage of it came into use only in the latter decades of the twentieth century.

²⁸ Shousha, T., et al., “Immunohistological study of oestrogen receptors in breast carcinomas that are biochemically receptor negative” *J Clin Pathol* 1990; 43(3): 239-42; Transcript of testimony, Dr. David Dabbs, September 15, 2008, pp. 137-139; Exhibit P-2621.

²⁹ Esteban et al. “Quantitative immunohistochemical assay for hormonal receptors: technical aspects and biological significance” *J Cell Biochem Suppl* 1994; 19: 138-42; Pertschuk et al. “Estrogen receptor immunocytochemistry: the promise and the perils” *J Cell Biochem Suppl* 1994; 19: 134-7; Transcript of testimony, Dr. David Dabbs, September 15, 2008, pp. 138-139; Exhibit P-2621.

³⁰ Transcript of testimony, Dr. Frances O’Malley, June 23, 2008, pp. 7-8 and pp. 9-10; Exhibit P-1728.

³¹ See, for example, Exhibit P-1720 and articles referenced therein; see also Exhibit P-2621, p. 2, and references to an understanding of the hormone involvement in breast cancer in the late 1800s and early 1900s.

Hormone Receptor Testing

Different types of drug-based anti-hormonal treatment have evolved over time. Tamoxifen is a selective estrogen receptor modulator, and acts as described above. It is still the anti-hormonal drug treatment of choice for menopausal breast cancer patients. Other anti-hormonal drugs, known as aromatase inhibitors (which include drugs such as Letrozole, Anastrozole, and Exemestane), work best in post-menopausal patients whose circulating estrogen no longer comes directly from the ovaries, but from the conversion (by the aromatase enzyme) of androstenedione³² (a hormone) into estrogen. The aromatase inhibitors prevent the aromatase enzyme from converting androstenedione to estrogen, thus decreasing the amount of circulating estrogen available to bind to the estrogen receptors and initiate tumour cell proliferation. Aromatase inhibitors became generally available as a treatment option for local oncologists in the early 2000s.³³

A patient's tumour hormone receptor profile provides her or his physician with information as to the patient's prognosis. The presence or absence of hormone receptors in tumour cells is a predictive factor that informs a physician as to how likely the patient is to respond to a certain treatment. For example, a patient whose breast cancer tumour is ER positive has a 10 to 15 percent overall survival benefit over those patients with ER negative tumours.³⁴ PR is itself an independent prognostic factor.³⁵ Approximately 70 percent of patients with ER positive disease will have a statistically significant clinical response to anti-hormone therapy, while 85 percent of patients with ER negative disease will show no response to anti-hormone therapy.³⁶ A patient who is both ER and PR positive has a greater chance of responding to anti-hormone therapy than a patient who is ER positive/PR negative or ER negative/PR

³² Androstenedione – “an androgenic steroid produced by the testis, adrenal cortex, and ovary, occurring as two types, Δ 4-androstenedione and Δ 5-androstenedione. Androstenediones can be converted metabolically to testosterone and other androgens” (*Dorland's*).

³³ Exhibit P-2610; Transcript of testimony, Dr. Kara Laing, September 9, 2008, pp. 20-27; p. 96.

³⁴ Transcript of testimony, Dr. Frances O'Malley, June 23, 2008, pp. 14-16.

³⁵ Transcript of testimony, Dr. David Dabbs, September 15, 2008, p. 135.

³⁶ Transcript of testimony, Dr. Frances O'Malley, June 23, 2008, pp. 14-16.

positive. Even in the absence of anti-hormone treatment, hormone-receptor-positive patients have a better prognosis.³⁷

Steps in the ER/PR IHC Testing Process

IHC is used as a tool to differentiate tumours, classify types of cancers, identify cancerous cells, and detect numerous different types of diagnostic³⁸ and prognostic³⁹ proteins in human tissue.⁴⁰ Most IHC stains, including those for ER and PR, are used, along with other information, to confirm a diagnosis made using a hematoxylin and eosin stain, or to distinguish features relating to a previous diagnosis.⁴¹

Pre-Analytical – Tissue Handling and Fixation

The process of IHC testing begins with a physician who determines that an analysis using IHC is required in relation to care of a patient. A tissue specimen is obtained from a patient; in the case of breast cancer, this is usually done by means of a core or excisional biopsy or by using tissue obtained during a mastectomy.

Core biopsies involve removal of a very small piece of tissue, and are usually done when an abnormality is seen on a mammogram.⁴² There are several different types of mastectomies. A total or simple mastectomy removes the entire breast, including the nipple and skin. Generally, lymph nodes and muscle under the breast are left in place with this procedure. A radical mastectomy removes the entire breast, the nipple,

³⁷ Transcript of testimony, Dr. Kara Laing, September 9, 2008, pp. 81-82; Transcript of testimony, Dr. Adam Brufsky, October 6, 2009, pp. 40-44.

³⁸ Diagnosis – “1. the determination of the nature of a case of disease. 2. the art of distinguishing one disease from another” (*Dorland’s*).

³⁹ Prognosis – “forecast as to the probable outcome of an attack of disease; the prospect as to recovery from a disease as indicated by the nature and symptoms of the case” (*Dorland’s*).

⁴⁰ Tissue – “an aggregation of similarly specialized cells united in the performance of a particular function” (*Dorland’s*).

⁴¹ Based on descriptions in the Submission of Eastern Health, para. 60.

⁴² Mammogram – “a radiograph of the breast”; Radiography – “the making of film records (radiographs) of internal structures of the body by passage of x-rays or gamma rays through the body to act on specially sensitized film” (*Dorland’s*); Transcript of testimony, Dr. Frances O’Malley, June 23rd, 2008, p. 24.

skin, some lymph nodes and the muscle under the breast, while a modified radical mastectomy is similar to a radical mastectomy, but differs in that the muscle under the breast is left in place.⁴³ However tissue specimens are obtained, they must be preserved and prepared through a pre-analytical process before IHC can be performed.

When breast tumour tissue is removed from the body, it is important that the tissue be properly preserved (“fixed”)⁴⁴ and handled (“processed”) prior to any analysis, including IHC. The tissue must be fixed using a fixation process that prepares the specimen to withstand further processing and preserves the cellular structure of the tissue as much as possible. When tissue samples are removed from the patient, they are typically immersed in liquid formalin⁴⁵ fixative in the operating room or other setting. Tissue samples are then transported to the pathology laboratory where a gross⁴⁶ examination of the tissue (commonly referred to as “grossing”) is performed by a pathologist or, in some cases, a pathologist’s assistant or a senior technologist. A description of what is observed during the grossing process is recorded in the pathology report.⁴⁷

To be effective and reliable, the fixation process needs to be standardized and uniform. It is important that tissue specimens be placed in fixative immediately after their removal from the body, and that the specimens spend the appropriate amount of time in the fixative, depending on the size of the specimen and the volume of fixative in

⁴³<http://www.cancer.ca>

⁴⁴ Fixative – “a fluid, often a mixture of several reactive chemicals, into which histological or cytological specimens are placed so that, by processes such as denaturation and cross-linking of proteins, autolysis is prevented, the specimen is hardened to withstand further processing, and the specimen is preserved in a close facsimile of the living state in regard to both cellular morphology and the location of subcellular constituents” (*Dorland’s*).

⁴⁵ Formalin – “a formaldehyde solution; a solution of formaldehyde in water, containing not less than 37 per cent of formaldehyde; used as a disinfectant and as a preservative and fixative for pathologic specimens. Called also formol” (*Dorland’s*).

⁴⁶ Gross – “1. coarse or large. 2. visible to the naked eye without the use of magnification; called also macroscopic” (*Dorland’s*).

⁴⁷ Submission of Eastern Health, para. 51.

which it is immersed.⁴⁸ To ensure fixation is adequate, large tissue specimens must also be sectioned or sliced using five to ten millimetre spacing (often referred to as “breadloafing”) to allow the formalin to diffuse (penetrate) throughout the entire specimen. When this procedure is not properly performed, the fixative does not penetrate the specimen quickly enough to preserve properly the innermost tissue of the specimen. It is very important to note that mere penetration of the tissue by formalin does not equate to fixation of the tissue, as simple exposure of the tissue cells to formalin is a necessary but not sufficient condition for proper fixation. Fixation is a chemical process involving the creation of methylene bonds due to a formaldehyde chemical reaction that only occurs over periods of time measured in numbers of hours after the initial exposure of individual tissue cells to formalin, as it penetrates the tissue.⁴⁹

After fixation, tissue specimens must be dehydrated, meaning the water must be removed from the tissue. Placing the tissue in a series of ethanol baths completes this process. Specimens are then washed in xylene⁵⁰ to remove the alcohol. When a tissue processor (i.e., a machine) is used, the process of dehydration and paraffin-embedding begins with the sections (or pieces) of tissue being cut small and thin enough to be placed in small plastic cassettes. The cassette holds the tissue and keeps it in the proper position so that it can eventually be placed in liquid paraffin to create a paraffin block that contains the tissue specimen. The process of paraffinization is performed using an automated tissue processor; this machine progressively exposes the tissue in the cassette to a series of solutions.

⁴⁸ The recommended volume is at least seven times the volume of formalin to the volume of the specimen. Specimens should sit in fixative between six and forty-eight hours, depending on the size of the specimen. Most specimens will require 24-48 hours; the lower range will only apply to small core biopsies; Transcript of testimony, Dr. Frances O'Malley, June 23, 2008, pp. 20-23.

⁴⁹ Exhibits P-3358 and P-3634; Transcript of testimony, Dr. David Dabbs, September 15, 2008, pp. 254-256.

⁵⁰ Xylene - a mixture of all three isomeric hydrocarbons, C₆H₄(CH₃)₂, from methyl alcohol or coal tar, with uses including solvent and clarifier for microscopy, protective coating, and in various syntheses (Adapted from *Dorland's*).

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The cassettes of tissue are placed in a sample basket, and the baskets are then loaded into the automated tissue processor. A tissue processor typically holds 150 to 300 cassettes per load or processing cycle. Once the machine is set to run, the cassettes in the basket are sequentially exposed to a series of processing reagents and molten paraffin. These reagents and paraffin are moved into and out of the retort⁵¹ through the use of vacuum and pressure. All reagents are introduced through the top of the retort; this is called a “pump-in.” Reagents are all drained from the bottom of the retort. The processing reagents, in order, are 10% neutral buffered formalin, six graded ethanols (65% - 100%), two baths of xylene, and four baths of paraffin; the total processing time for a routine run is approximately 12.7 hours. The tissue processor has customizable software that the laboratory can use to meet its needs at any particular time. Various protocols can be programmed, including a routine overnight run, a weekend run, specific runs for long (three- or four- day) weekends, rush runs with formalin, and rush runs with no formalin. For optimal operation of the tissue processor, proper cleaning of the machine is critical. Proper placement of tissue specimens is vital to optimal processing. Solutions must be replaced and exchanged as needed, which is best determined by the volume of specimens a laboratory is processing. Paraffin also needs to be replaced, and it is important not to overfill the paraffin containers in the machine. The water bottle needs to be changed on the machine daily, as it absorbs formalin and alcohol vapours from the exhaust fumes during processing.⁵²

Once tissue processing is complete, the resulting paraffin-embedded tissue is usually referred to as a “block.” These tissue blocks

⁵¹ Retort - “an enclosed chamber that holds the tissue specimens and in which processing occurs” Exhibit P-3624, p. 5 (*Tissue-Tek® VIP™ 5 Vacuum Infiltration Processor Operating Manual*).

⁵² Exhibits P-3624 and P-3038. It should be noted here that the processing protocol described is as recommended in the manual for the *Tissue-Tek® VIP™ 5 Processor*. Experts testified, as described elsewhere in this report, that none of the four regional health authorities were using optimal protocols on their tissue processors. The recommended protocol of these experts differs slightly from the one described here, as they call for three baths of xylene.

can be stored for many years. Eastern Health's policy is to retain paraffin-embedded tissue blocks for 20 years.⁵³

Analytical - Slide Preparation and Staining

In order to create slides from the tissue embedded in the paraffin block, technologists cut thin slices, ideally at 4-5 microns,⁵⁴ of the tissue from the blocks using an instrument called a microtome.⁵⁵ The thin slices, known as "sections," are then placed on a glass slide to allow for staining and review under the microscope. It is critical that water is removed from the section on the slide; this can be done either by drying the slide overnight or by baking it in a temperature-controlled oven. If water is retained in the section before the tissue is subjected to IHC processing, the tissue can lift off and partially degenerate, creating holes in the tissue or folded tissue on the slide.⁵⁶ Either eventuality precludes ideal results in the IHC process, as folds or missing tissue will interfere with the ability of a pathologist to assess the slide accurately for hormone receptor positivity.

Some slides are routinely stained using a hematoxylin and eosin ("H&E") staining method. This stain allows the cell structure within the tissue to be examined under a microscope. By observing cell structures on H&E stained tissue, a pathologist can often determine whether or not disease is present, and provide a diagnosis.⁵⁷

The appropriate IHC stains to be used are generally determined by a pathologist. For each IHC stain, proper reagents and protocols must be determined. Correct performance of the protocol using appropriate external and internal controls produces a result (i.e., stained slide) that is then evaluated, and a report is prepared.

⁵³ Submission of Eastern Health, para. 52.

⁵⁴ 1 micron = 0.001 millimeter.

⁵⁵ Microtome - "an instrument for cutting thin slices of tissue for microscopical study" (*Dorland's*).

⁵⁶ Transcript of testimony, Dr. David Dabbs, September 15, 2008, pp. 148-151.

⁵⁷ Transcript of testimony, Dr. David Dabbs, September 15, 2008, pp. 148-151.

Analytical - IHC

Immunohistochemistry is based on the principle of antigen and antibody interaction. Protein from human cells is injected into animals (usually mice or rabbits), and the animal produces antibodies (also proteins) against the human cell proteins. Each antibody recognizes a specific antigen that is unique to its target.⁵⁸ Estrogen receptors and progesterone receptors are antigens⁵⁹ that antibodies can be created to target. Once antibodies and antigens react,⁶⁰ they can be examined microscopically to detect the presence or absence of the antigen (in this case, ER or PR) as indicated by brown-coloured staining of individual cells in the nucleus.

The process of formalin fixation masks (i.e., makes it difficult to detect) antigens. Antigens must, therefore, then be retrieved through a procedure that enhances the ability of the antibody to access the antigen. Slides need to be de-waxed before antigen retrieval can occur. De-waxing is performed using a series of baths in which paraffin slides are immersed for set amounts of time, depending on the protocol used. These baths consist of xylene (usually two to three washes), 95% ethanol, 70% ethanol, and deionized water.

The slides are put through a process of antigen retrieval⁶¹ because the process of formalin fixation of tissue hides the antigens from the antibodies by forming methylene bridges that mask antigen sites.⁶² Not

⁵⁸ Exhibit P-2171.

⁵⁹ Antigen - any substance capable, under appropriate conditions, of inducing a specific immune response and of reacting with the products of that response, that is, with a specific antibody. Antigens may be soluble substances or particulate; however, only the portion of the protein or polysaccharide molecule known as the antigenic determinant combines with antibody or a specific receptor on a lymphocyte (Abbreviated as Ag.) (*Dorland's*).

⁶⁰ Antigens stimulate antibody production, and are recognized by receptors. The part of the antigen that comes into contact with the antigen receptor is called the epitope or antigenic determinant. See Exhibits P-1425 and P-2171.

⁶¹ "Antigen retrieval is the concept of recovering lost immuno reactivity through exposure to heat or enzyme"; Exhibit P-2171, p. 17.

⁶² Exhibit P-2171, p. 16.

all antibodies require antigen retrieval; among those that do, some respond best to either heat-induced epitope retrieval or proteolytic-induced epitope retrieval.⁶³

Antigen-antibody interactions are heat-sensitive; in early antigen retrieval protocols, the tissue sections were boiled at 95-100 degrees Celsius to “unmask” the sites.⁶⁴ All methods used for antigen retrieval of ER and PR at Healthcare/Eastern Health were forms of heat-induced epitope retrieval (“HIER”).⁶⁵

Initially at Healthcare, antigen retrieval was performed by boiling water (95-100 degrees Celsius) on a hotplate, placing the appropriate buffer (at that time a citrate buffer) in a coplin jar (a glass jar that holds slides in position), and placing the coplin jar into the boiling water on the hotplate. The slides would be kept at that temperature for 20-30 minutes, removed from the boiling water, and allowed to sit for 30 minutes at room temperature at the General Hospital laboratory; the protocol followed was obtained from the antibody supplier’s specification sheet.⁶⁶ A list was available in the laboratory that specified which antibodies required antigen retrieval and which did not. If it was unclear whether an antibody required antigen retrieval, the antibody specification sheet (“spec” sheet) would contain this information.⁶⁷

When the DAKO Autostainer was introduced into the General Hospital pathology laboratory in 1998, the antigen retrieval process did not fundamentally change.⁶⁸ On the DAKO instrument there were two antigen retrieval solutions; slides being tested for ER and PR receptors required the use of a citrate buffer at pH 6. This buffer required 95-99 degrees centigrade and 20-40 minutes of heat, along with 20 minutes at room temperature. According to the testimony of laboratory personnel,

⁶³ Transcript of testimony, Kenneth Green, July 9, 2008, pp. 71-72; Exhibit P-2171, p. 17.

⁶⁴ Exhibit P-2171; pp. 16-18.

⁶⁵ Submission of Eastern Health, p. 49.

⁶⁶ Transcript of testimony, Peggy Welsh, July 8, 2008, pp. 134-137; Transcript of testimony, Mary Butler, July 16, 2008, pp. 175-176; Transcript of testimony, Kenneth Green, July 9, 2008, p. 71.

⁶⁷ Transcript of testimony, Kenneth Green, July 9, 2008, p. 70.

⁶⁸ Transcript of testimony, Mary Butler, July 16, 2008, pp. 175-176.

the slides were heated for 30 minutes and spent 30 minutes at room temperature.⁶⁹

In 1999 the General Hospital laboratory obtained a water bath, at which point they discontinued using the hot plate. The advantage of a water bath was that it could be set at the required temperature, and the antigen retrieval process was performed as before, without the necessity of manually using a thermometer to monitor the temperature to ensure the hotplate maintained it within the specified narrow range. The water bath allowed for a more constant temperature. The use of a water bath in the ER/PR testing process continued until the Ventana Benchmark came into use at the General Hospital around April 2004.⁷⁰

After the process of antigen retrieval is complete, antibodies are used to detect the hormone receptors. Standard IHC involves applying a primary antibody, incubating it on the slide for the appropriate amount of time (as determined by the optimization process), applying a secondary antibody, applying the detection complex (used to identify/detect the secondary antibody),⁷¹ and, finally, developing the reaction product with chromogen, counterstaining, dehydrating, and placing a cover slip on the slide.⁷² Each of the antibodies, the detection complex, and the chromogen are incubated on the slide for an appropriate amount of time, and each step is followed by rinsing the tissue with buffer before the next step begins.

A validation process must occur for each antibody used. Dr. Clive Wells, a consultant histopathologist with a special responsibility for breast pathology at Barts and the London NHS Trust, London, England testified with respect to optimizing techniques and validation of processes. He confirmed that differences in the particular antibody used to test for ER or PR should not account for changes in test results:

⁶⁹ Transcript of testimony, Kenneth Green, July 9, 2008, pp. 74-78; Exhibit P-2176, p. 5.

⁷⁰ Transcript of testimony, Peggy Welsh, July 8, 2008, pp. 134-137; Transcript of testimony, Mary Butler, July 16, 2008, pp. 175-176.

⁷¹ Transcript of testimony, Trish Wegrynowski, June 24, 2008, p. 120.

⁷² Exhibit P-1425, pp. 26-27.

The Commissioner:

Q. ...if you assume optimal fixation and optimal processing in two laboratories which might use different antibodies because they have chosen for perhaps good reason to use one antibody in one laboratory and another, assume, for the moment, both well recognized acceptable for use in this. Would you expect that the results would be statistically different in those two laboratories, testing the same sample?

Dr. Wells:

A. No, I would expect that with good fixation and with good technique and with good antibodies, they should be identical.⁷³

Dr. Emina Torlakovic, an Associate Professor at the University of Saskatchewan and Chair of the National Standards Committee/Immunohistochemistry for the Canadian Association of Pathologists, also testified about optimizing results. She confirmed that the use of different antibodies should not result in changed test results as “more than one method can lead to optimized result[s].”⁷⁴

A number of different methods are available to perform the analytic aspect of IHC. In the very early days, when at the General Hospital ER and PR testing by IHC was being performed entirely manually, the ABC method was used. During the period when the DAKO instrument was used for ER and PR IHC testing, an EnVision polymer-based system was used. After the Ventana was introduced, a streptavidin-biotin⁷⁵ (SA-B) system was used; it still is used in St. John’s.

After the antibody reaction is completed, the detection phase must occur; the complex of antibody bound to the antigen has to be made visible. Several methods, including the streptavidin-biotin method, have been used in St. John’s. When IHC was first introduced in St. John’s in

⁷³ Transcript of testimony, Dr. Clive Wells, October 27, 2008, pp. 91-92.

⁷⁴ Transcript of testimony, Dr. Emina Torlakovic, October 9, 2008, pp. 290-295. Dr. Torlakovic is also a member of the American Society of Clinical Oncology and College of American Pathologists Expert Panel for “Guidelines on Hormone Receptor Testing in Breast Cancer.”

⁷⁵ Biotin - is a water soluble B-complex vitamin. Avidin is a protein derived from egg white that has a strong affinity for biotin. Streptavidin is a highly stable analogue of avidin; see Exhibit P-1425.

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1997, the peroxidase-antiperoxidase (PAP)⁷⁶ method was used. The PAP method involved the following steps:

- Creation of slides;
- De-paraffinizing and re-hydrating processes;
- Application of the primary antibody, washing, and incubation;
- Application of the secondary antibody, binding to the primary;
- Peroxidase staining “revealed” by applying DAB (diaminobenzidine), which stained the secondary antibody;
- Application of counterstain of hematoxylin to make the cell structure visible.⁷⁷

By the fall of 1997, ER and PR IHC testing was performed in St. John’s with the DAKO instrument, using kits purchased from DAKO that included all the necessary antibodies and reagents.⁷⁸ The DAKO Autostainer is an instrument that consists of a rectangular chamber with a transparent cover; there are slots inside the chamber to hold 48 slides. A robotic arm with an automated pipette is part of the autostainer, and an attached computer is programmed with protocols for each antibody used. The computer controls the movements of the robotic arm. The technologist using the computer console selected the protocol to be run, and an attached printer produced a “reagent map” that illustrated the correct slots in which the technologist would place the various antibodies, reagents, and solutions. The robotic arm with attached pipette would draw the antibody (or reagent or solution, as appropriate) from the appropriate slot and then apply that fluid in the programmed quantities to the various slides. The Autostainer washes the slides off after the appropriate incubation time, as outlined in the protocol selected.⁷⁹ With this process, laboratory personnel controlled a number of

⁷⁶ Peroxidase-antiperoxidase technique – “a technique for detecting antigen or antibody in tissue sections. The tissue section is incubated with rabbit antibody specific for the antigen to be detected, followed by an excess of antirabbit IgG. A complex of horseradish peroxidase and rabbit antiperoxidase is added; these are linked to the antigen-bound antibody by the antirabbit IgG. The PAP complexes are then stained by incubation with a chromogenic substrate to produce a colored reaction product” (*Dorland’s*).

⁷⁷ Submission of Eastern Health, p. 30; Exhibit P-2193.

⁷⁸ Submission of Eastern Health, p. 35; Exhibit P-2150.

⁷⁹ Submission of Eastern Health, pp. 50-52.

aspects of each protocol, including antibody dilution, incubation times, and antigen retrieval.

The kit used with the DAKO Autostainer for detecting antibodies to the hormone receptors is known as the EnVision detection system. This kit requires HIER using a target retrieval solution specific to the primary antibody being used. The EnVision system itself is a two-step process based on an HRP⁸⁰-labelled polymer conjugated to secondary antibodies. It claims to be advantageous over other kits that use avidin-biotin, as the polymer is said to be less likely to produce endogenous⁸¹ staining. Endogenous peroxidase activity needs to be quenched by using a peroxidase block (five-minute incubation); the DAKO Peroxidase Block is included with the kit. Non-specific endogenous staining will appear as a diffuse cytoplasmic staining that is eliminated by proper blocking.⁸² Slides are loaded onto the DAKO instrument and the primary antibody is applied; each slide is incubated for the appropriate length of time, depending on the particular antibody (usually 10-30 minutes). Slides are then incubated with the labelled polymer using a 10-30 minute incubation. Staining involves a 5-10 minute incubation with DAB+ substrate chromogen (also supplied with the kit). In between steps of the process, the slides are rinsed with a buffer solution⁸³ to prepare them for the next step. At the end of the process, slides are rinsed with distilled water. Slides are then counterstained in hematoxylin.⁸⁴

In April 1998, the laboratory switched to using concentrated antibodies that required laboratory personnel to dilute the antibody for use in IHC.⁸⁵ The antibodies used were the 1D5 clone for ER (1997 to April 2004), the PR 1A6 clone (1997 to April 1999), and the PGR 636 clone

⁸⁰ Horseradish peroxidase - "peroxidase LsqbEC 1.11.1.7Rsqb (q.v.) isolated from horseradish (*Armoracia lapathifolia*); used as a reagent in biochemical assays" (*Dorland's*).

⁸¹ Endogenous - "1. growing from within. 2. developing or originating within the organism, or arising from causes within the organism. Also called endogenic" (*Dorland's*).

⁸² Exhibit P-1764.

⁸³ 1x Tris-buffered Saline (TBS) solution; Exhibit P-2176.

⁸⁴ Exhibit P-2176.

⁸⁵ Submission of Eastern Health at p. 47; Exhibit P-2150.

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for PR (April 1999 until April 2004).⁸⁶ A number of different reagents, solutions, and detection kits were also used during this time. While it is reasonable to infer these were the various reagents, solutions, and detection kits used,⁸⁷ it is important to note that no written records were systematically kept of what was in use at any particular time:

- Envision Detection Kit (November 1997 – December 2003)
- Envision+ (December 2003 – April 2004)
- Universal Blocking solution (August 1998 – April 2004)
- ER/Biotin Block (November 1997)
- Antibody Dilution Buffer (November 1998 – April 2004)
- Target Retrieval Solution (November 1998 – April 2004)
- Target Retrieval Solution with high pH (August 1998 – April 2004)
- Tween (June 1998 – April 2004)
- Protein Block (December 2002 – April 2004)
- DAB Tablets (1997 – June 1998)
- DAB Substrate (June 1998 – April 2004)
- DAB Chromogen/Substrate (June 2003 – April 2004)
- TBS Buffer Tablets (1997 – July 2001)
- TBS Buffer (July 2001 – April 2004)
- LSAB+ (February 2003 – April 2004)⁸⁸

In April 2004, use of the DAKO Autostainer was discontinued and the Ventana Benchmark was implemented. The Ventana Benchmark reduced the number of steps in the IHC process that involved human intervention, thus bringing higher levels of consistency to test procedures. The Ventana instrument had “onboard” antigen retrieval, and also allowed specimens to be bar-coded.⁸⁹ The Ventana instrument allowed the use of pre-diluted antibodies, eliminating the possibility of human error in the dilution process. When the Ventana instrument was

⁸⁶ Exhibit P-2150.

⁸⁷ Based on the summary prepared by Terry Gulliver of purchases during the relevant time frames – see Exhibit P-2150.

⁸⁸ Exhibit P-2150.

⁸⁹ Submission of Eastern Health, p. 78; Transcript of testimony, Dr. Donald Cook, July 7, 2008, pp. 19-20; P-2150; P-1906; Transcript of testimony, Kenneth Green, July 9, 2008, p. 79.

introduced, the 6F11 clone (for ER) and the 1E2 clone (for PR) were the antibodies adopted.⁹⁰

The Ventana Benchmark onboard antigen retrieval had four options for the antigen retrieval process – “short” (eight minutes of incubation in the buffer), “mild” (30 minutes of incubation in the buffer), “standard” (60 minutes of incubation in the buffer), and “extended” (90 minutes of incubation in the buffer). The machine itself has metal pads to place slides on (separate pads for each slide); the pads are heated to the required temperature by the machine (the temperature is controlled automatically) and the buffer is sprayed onto the slide.⁹¹ The protocol chosen by Healthcare called “CC1 mild,”⁹² uses an EDTA⁹³ buffer solution (pH 8). Because the slides are not “boiled,” but rather laid on metal pads and sprayed with buffer, the Ventana heating process is considerably “gentler” on the tissue than the hotplate/water bath manual methods for antigen retrieval. The standardization of antigen retrieval which the Ventana permitted was a significant change that occurred when it replaced the DAKO instrument.⁹⁴

With the implementation of the Ventana Benchmark for ER/PR testing, the detection system changed to a Ventana kit called the “iVIEW DAB.”⁹⁵ This kit uses biotinylated secondary antibodies to locate primary antibody bound to the antigen (hormone receptors). This binding is then followed by the binding of Streptavidin-HRP conjugate. The bound complex is then made visible with hydrogen peroxide substrate and DAB chromogen. The dark brown precipitate formed by this interaction is easily viewed using light microscopy.⁹⁶

⁹⁰ Exhibit P-2150.

⁹¹ Transcript of testimony, Les Simms, July 16, 2008, p. 148-149.

⁹² CC1 - manufacturer’s name for antigen retrieval; Transcript of testimony, Kenneth Green, July 9, 2008, pp. 74-78.

⁹³ EDTA - ethylenediaminetetraacetic acid and is a commonly used buffer solution; Transcript of testimony, Kenneth Green, July 9, 2008, pp. 74-78.

⁹⁴ Transcript of testimony, Kenneth Green, July 9, 2008, pp. 74-78 and p. 217.

⁹⁵ Exhibits P-1605 and P-1746.

⁹⁶ Exhibit P-1764.

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The Ventana Benchmark automatically adds antibody and reagents to a given slide according to whatever protocol is programmed into the instrument. The appropriate antibody dispenser and detection kit dispensers, and all other required reagents are loaded onto a reagent carousel in the Ventana instrument. Each slide in this system is labelled with a bar code, which is applied prior to deparaffinization of the tissue. In the Ventana instrument, paraffin is removed from the slides during an eight-minute incubation at 75 degrees Celsius. Endogenous peroxidase activity is blocked using an inhibitor solution incubated for four minutes at 42 degrees Celsius. The specific antibody is then applied and incubated for four to 32 minutes (as appropriate, depending on the antibody) at 42 degrees Celsius. Biotinylated secondary antibody is applied for eight minutes, also at 42 degrees. Streptavidin-HRP is applied to the slides for eight minutes (42 degrees), and the iVIEW DAB solution is then mixed with the hydrogen peroxide solution on the slide for eight minutes at 42 degrees. DAB enhancer is applied for four minutes at 42 degrees, and counterstain, if selected, is applied for four minutes at 42 degrees. After each incubation step, the machine washes the slides before the addition of the next antibody or reagent, as appropriate.⁹⁷

Post-Analytical - IHC

Finally, IHC slides are analyzed by a pathologist, who interprets the staining of the cells and the cell structure itself for diagnosis or other assessment.⁹⁸

For reporting results of ER and PR IHC testing, different methods are used. In Newfoundland and Labrador, reporting of ER/PR by pathologists was historically done about half the time simply by using a designation of “positive” or “negative,” while in the remaining cases pathologists reported ER/PR results by referring to the percentage of cells that stained for ER and the percentage of cells that stained for PR.

Some institutions in North America and elsewhere quantitate the ER/PR result by using such methods as the Allred score or the H score.

⁹⁷ Exhibits P-1605, P-2310, P-2171, P-1764, and P-1425.

⁹⁸ Exhibits P-1728, P-1425, and P-2171.

The Allred score takes into account both the proportion and intensity of staining of cells on the slide. The factors of proportion of cells and intensity of staining are given a score of between zero and three for intensity, and between zero and five for proportion of cells; these scores are added to generate the Allred score. The use of this method of reporting has been validated and correlated with patient outcomes.⁹⁹

The H score (for “histochemical”), introduced by McCarty in 1985,¹⁰⁰ is the product of the proportion of cells stained multiplied by the intensity of the staining. The proportion of stained cells in the nucleus is read as a percentage. This number between 0 and 100 is multiplied by a value between 0 and 4 that is determined for the staining intensity. The H score method was the first effort to quantitate results from IHC, and remains in use in reputable medical institutions today. The use of the H score has been validated and correlated to outcomes. It is useful from a clinical perspective; as Dr. David Dabbs pointed out in his testimony, a patient with an H score of 350 for ER should benefit from anti-hormonal therapy. A patient with an H score of 60 may benefit from anti-hormonal therapy, but will likely benefit less than the patient with the H score of 350.¹⁰¹ The use of an intensity of staining and proportion of staining scoring system such as the H score or the Allred score addresses consensus recommendations that both the proportion of positive tumour cells and the intensity of nuclear staining should be considered when ER IHC test results are reported.¹⁰²

Consensus Statements

Consensus statements exist to provide guidance in areas that are often uncertain; experts recognize the need for agreement and guidelines. In 2000, the National Institutes of Health published a Consensus Statement on Adjuvant Therapy for Breast Cancer, arising out of a

⁹⁹ Transcript of testimony, Dr. David Dabbs, September 15, 2008, pp. 258-260; Transcript of testimony, Dr. Frances O'Malley, June 23, 2008, pp. 36-37.

¹⁰⁰ McCarty et al. “Estrogen Receptor Analysis: Correlation of Immunohistochemical and Biochemical Methods” 1985; *Arch Pathol Lab Med* 109: 716-21; Exhibit P-2621.

¹⁰¹ Transcript of testimony, Dr. David Dabbs, September 15, 2008, pp. 131-133; Exhibit P-2621.

¹⁰² Transcript of testimony, Dr. David Dabbs, September 15, 2008, p. 140; Exhibit P-2621.

conference in November of that year. The NIH Consensus Statement recommended that “any nuclear ER” allow a patient to be eligible for endocrine therapy.¹⁰³ Other recommendations included the optimization of the IHC assay for ER so that staining can best capture the full range of distribution and intensity of the ER, and negative ER results on needle core biopsies should be confirmed by repeating the test on a subsequent surgical excision.¹⁰⁴

In 2005, a consensus panel of experts met¹⁰⁵ and developed a series of guidelines and recommendations for selection of adjuvant systemic treatments for early breast cancer. The expert panel affirmed that the first consideration in selecting adjuvant therapy in early breast cancer was hormone responsiveness, and stated that patients whose breast cancer cells express hormone receptors (diagnosed using proper immunohistological or biochemical methods) are more likely to benefit from endocrine therapies (such as tamoxifen).¹⁰⁶

Most Recent Recommendations for ER Testing

In 2008, a meeting of an ad hoc committee of pathologists, technologists and scientists was held to develop and publish standardization of testing recommendations that were intended to optimize ER testing.¹⁰⁷ This document recognized ER as “the single most important therapeutic predictive factor in breast cancer.” It also noted the importance of pre-analytical variables in standardization of any laboratory assay involving tissue fixation and processing. Lack of standards in this area was identified by the ad hoc committee as a major cause of variability in IHC results between laboratories. The 2008 recommendations as summarized by Dr. Dabbs are:

¹⁰³ Exhibit P-2621.

¹⁰⁴ Transcript of testimony, Dr. David Dabbs, September 15, 2008, pp. 175-178; Exhibit P-2621.

¹⁰⁵ The ninth St. Gallen (Switzerland) expert consensus meeting.

¹⁰⁶ Exhibit P-2611.

¹⁰⁷ Exhibit P-3634; The authors are recognized experts in their fields and represented academic centres, reference laboratories, and a number of agencies. One of the authors was Dr. David Dabbs, who testified at the Commission of Inquiry and is a recognized expert in the field of IHC.

1. Resection specimens must be sectioned fresh, as soon as possible, preferably 0.5 cm thick, placed in fixative as quickly as possible (in less than 1 hour), and the time in formalin should be recorded. Tissue sections must be immersed in an adequate volume of fixative (tissue to fixative ratio of 1:20) within a maximum of one hour from removal and acquisition. Normal tissue should be included with tumour in same cassette, if possible.
2. Breast core biopsies should be fixed and processed in an identical manner to excision specimens; the time from specimen acquisition to the time the specimen is placed into formalin should be recorded.
3. Only 10% aqueous phosphate buffered formalin, pH 7-7.4, should be used as a fixative for breast tissue samples.
4. The amount of time samples spend in 50% phosphate buffered formalin should be standardized for all breast specimens to ensure adequate and uniform fixation. This time should be a minimum of 8 hours and should not exceed 72 hours. Optimizing this time promotes antigen retrieval standardization and avoids alcohol fixation.
5. If there is a clinical suspicion of breast cancer that may need ER analysis and a fine needle aspirate is performed, then all efforts should be made to collect a portion of the cytology specimens in formalin for hormone receptor analysis.
6. Breast cancer specimens should be processed in conventional processors.
7. The first formalin containers in the tissue processor should always be newly replenished, on a daily basis, since the amount of time in formalin includes the processor exposure to formalin.
8. It is strongly recommended that none of the tissue processor solutions, excluding paraffin, exceed 37 degrees Celsius if the processor contains breast tissue for potential ER and other biomarker testing, since higher temperatures can damage tissue.
9. Paraffin and tissue processors or embedding centres should not be warmed over 60 degrees Celsius and tissue should not be kept in heated paraffin for extended periods of time.
10. Include a designated field on the requisition sheet for recording time into formalin and time out. Time in formalin can be dictated

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- into a gross description. Time of collection recording is encouraged at clinic sites where biopsies are performed.
11. The IHC ER assay should be performed with one of three antibody clones (1D5, 6F11, SP1) using standardized methods, preferably using FDA-approved test kits (which standardize the actual platform).
 12. Positive and negative test controls¹⁰⁸ should be included with every ER IHC batch run.
 13. A commonly employed threshold for positive results for ER IHC assays is 1% positive tumour cell with a 1+ or greater signal. Standardizing interpretation is important, and for potential benefit from adjuvant endocrine therapy, the cut-off should be 1% positive tumour cells, with 1+ or greater signal.¹⁰⁹
 14. The interpretation of ER assay should include an evaluation of both the percent of positive tumour cell nuclei and the intensity of the staining reaction. Since the level of ER expression encompasses a broad dynamic range, optimization of the assay is important to capture properly the distribution and intensity of the staining.
 15. The intensity of staining should be recorded as weak (1+), moderate (2+), and strong (3+), and the percentage of cells demonstrating each of these categories of staining should also be recorded.¹¹⁰

Dr. Dabbs also testified on the importance of metrics.¹¹¹ He stated that “[i]t is highly desirable to maintain laboratory metrics for each

¹⁰⁸ Internal control = tissue or cells in the same section or a separate section from the same patient specimen as the test section – see Transcript of testimony, Dr. David Dabbs, September 15, 2008, p. 174.

¹⁰⁹ Transcript of testimony, Dr. David Dabbs, September 15, 2008, p. 176; Dr. Dabbs testified that the 2008 publication differs from the NIH consensus statement of the year 2000 by a very small amount (between zero and one percent) and many institutions, including his, still use zero as the threshold of positivity.

¹¹⁰ Transcript of testimony, Dr. David Dabbs, September 15, 2008, pp. 161-178; Exhibit P-3634.

¹¹¹ Transcript of testimony, Dr. David Dabbs, September 15, 2008, pp. 135-136: “...and by metrics I mean for any given laboratory the overall percent of patients who are ER positive and then you can break that down into the category that’s ER positive and PR positive, there will be a category that’s ER positive and PR negative, there will be a

prognostic predictive test result in order to monitor for potential analytic drift. For example, published literature indicates that 70 to 80 percent of breast cancers are ER positive. This should be a benchmark for each laboratory to monitor.”¹¹²

category that’s ER negative and PR positive, and then there will be the double negatives, the ER negatives and PR negatives.”

¹¹² Transcript of testimony, Dr. David Dabbs, September 15, 2008, p. 175; Exhibit P-3634.

Chapter Four

The IHC Story in St. John's: 1997-2005

The IHC Story in St. John's: 1997 - 2005

Dr. Mahmoud Khalifa

Dr. Mahmoud Khalifa practiced as a staff pathologist with Healthcare from 1995 to 1999, during which time he was instrumental in implementing the transition of ER and PR testing from the use of a biochemical assay to the IHC method using paraffin-embedded, formalin-fixed tissue.

Dr. Khalifa began his career practicing as a staff pathologist in Egypt, earning a Master's degree and PhD in pathology. After being awarded a Fullbright scholarship, he studied breast and gynecological pathology at the Armed Forces Institute of Pathology in Washington, DC. Following his scholarship tenure, he returned to Egypt to transfer the knowledge obtained during his time in the US. Just over a year later, he accepted an offer to research eye disease at the University of Maryland in Baltimore. Dr. Khalifa then moved to Oklahoma City, where he completed a residency in anatomic pathology. He became board certified in the United States, did a surgical pathology fellowship at George Washington University, and then worked as an instructor at Georgetown University Medical School, where he also practiced clinical pathology.

Dr. Khalifa arrived in St. John's in April 1995; he obtained his Canadian Royal College of Physicians and Surgeons certification shortly thereafter. In 1996 he became General Hospital pathology site chief with Healthcare, a position he held until he left Newfoundland and Labrador in June 1999. As a staff pathologist, Dr. Khalifa typically worked in his office at the General Hospital in the morning, then reported and signed out cases when slides arrived from the laboratory in the early afternoon. If, on his review, cases needed further investigation, he would order the requisite stains or further testing as required. He was also involved in research and in the training of residents in his capacity as an Assistant Professor with Memorial University of Newfoundland's medical school.

In 1995, the ER and PR status of breast tumours was being tested in St. John's through the use of the "biochemical assay" method. In this

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process, the surgeon excised the tumour, which was then dissected without microscopic examination. A section of the tumour (if it was in fact tumour tissue – without microscopic examination this would at times be difficult to determine) was sent immersed in liquid nitrogen directly to the chemistry laboratory; the pathology laboratory was not involved in the biochemical assay process. The chemistry laboratory converted the presumed tumour tissue by means of pulverization to a group of cells (an “emulsion”)¹ and tested them using the prescribed biochemical procedure. The results were reported by the General Hospital laboratory’s biochemistry section; depending on the level of hormone receptor expression, results were reported in levels (using actual numbers) and categorized by the biochemist as “negative,” “equivocal,” or “positive,” based on a numeric scale.

By the mid-1990s, many North American medical institutions had moved away from the biochemical assay for a number of reasons, including the fact that it was seen as a “crude” technique because of the mixing of benign² cells with malignant³ cells. This created uncertainty as to whether the hormone receptor status of the actual tumour was being analyzed. In the early 1990s, immunohistochemistry was being introduced in Oklahoma City (where Dr. Khalifa was working at the time), but was then not yet highly evolved, as it was still being performed on frozen sections. By 1994, when Dr. Khalifa worked at George Washington University, immunohistochemistry was being performed there on formalin-fixed, paraffin-embedded tissue. Dr. Khalifa came to believe during his time at George Washington University and Georgetown University that probably everybody was then using IHC for ER/PR analysis.

On his arrival in St. John’s in 1995, Dr. Khalifa was “very impressed” with both the number of IHC antibodies available in the

¹ Emulsion – “a mixture of two immiscible liquids, one being distributed in small globules throughout the body of the second. It is a colloid system in which both the dispersed phase and the dispersion medium are liquids, the dispersed liquid being the discontinuous phase and the dispersion medium the continuous phase” (*Dorland’s*).

² Benign – “not malignant; not recurrent; favourable for recovery” (*Dorland’s*).

³ Malignant – “1. tending to become progressively worse and to result in death. 2. having the properties of anaplasia, invasion, and metastasis; said of tumors” (*Dorland’s*).

General Hospital's clinical laboratory and the quality of work being done in the IHC laboratory.⁴ Shortly after his arrival, he learned that the biochemical assay was still used locally for ER and PR testing, a practice he viewed as less than optimal. He approached Dr. David Haegert, the Memorial University Discipline Chair and Clinical Chief of the Department of Laboratory Medicine, about pursuing the introduction of immunohistochemistry testing for ER and PR in St. John's.

Dr. Haegert supported Dr. Khalifa's initiative, as did the director of biochemistry. They considered how to go about locally instituting ER/PR testing using paraffin-embedded tissue, and Dr. Khalifa developed a plan. The priority they set was to ensure that ER and PR results achieved through immunohistochemistry would be comparable to those produced by the biochemical assay. Research was completed on which antibodies to purchase, since several were then available. They experimented with different kits (a kit is composed of a suitable antibody and the other chemicals required for the test),⁵ using various titrations⁶ and concentrations, until the testing conditions met the specifications of the manufacturer. This was done in parallel with the biochemical assay, which was used in St. John's until Dr. Khalifa and his colleagues were "fully comfortable" with the ER and PR immunohistochemistry process. When immunohistochemistry was locally first used, beginning in 1997, to conduct ER and PR analysis on patient tissue specimens, Dr. Khalifa read all the resulting slides, which practice continued until early March 1998. Clinicians were for a period receiving two reports on ER/PR – the traditional one from biochemistry and Dr. Khalifa's report on the IHC results. Dr. Khalifa felt that his colleagues, particularly oncologists, would be more comfortable with the results if they were able to "translate" the IHC results he was providing into quantities comparable to the results they were familiar with, based on the results of the biochemical assay. He therefore opted to use numbers and a reporting

⁴ Transcript of testimony, Dr. Mahmoud Khalifa, July 24, 2008, p. 54.

⁵ "Deciding on antibody/kit involved looking at the literature, seeing which clone is more popular, determining which must be purchased in a kit and which can be used with your own solution, cost, etc...." Transcript of testimony, Dr. Mahmoud Khalifa, July 24, 2008, p. 92.

⁶ "Determination of a given component in solution by addition of a liquid reagent of known strength until a given endpoint (e.g., change in color) is reached" (*Dorland's*).

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format by which both sets of results could be easily compared. He felt at the time that “conventional wisdom” in this field was that tamoxifen was a “tricky drug,” with such negative potential side effects (including increased risk of uterine and endometrial cancers) that his job was to provide a clear message to the oncologist or other treating physician with respect to the ER and PR results.⁷

During a meeting of Healthcare site chiefs and clinical chiefs on October 8, 1997, it was mentioned that physicians with the Newfoundland Cancer Treatment Research Foundation (NCTRF) cancer clinic preferred to see the biochemical assay done, and that standardized reporting of IHC results was a problem. Dr. Khalifa was asked to research the method of reporting IHC results for ER and PR used at other institutions across Canada, and to also seek feedback from clinicians at the NCTRF cancer clinic relating to the test itself. As a result of this discussion, Dr. Khalifa presented a report on a study he had performed with Dr. C. Pugh that demonstrated the correlation between a limited number of local IHC results (19 estrogen and 17 progesterone) and the corresponding results produced using the biochemical assay. The report dealt with certain test results during the nine-month period from January 1997 to September 1997. In presenting his report, Dr. Khalifa was attempting to demonstrate to his medical colleagues that the results from IHC testing were as valid as those they were used to receiving from a biochemical assay. In conducting and reporting this correlation study, Dr. Khalifa was not, it is important to note, attempting to validate the ER/PR test in IHC – by then, the use of IHC for ER/PR testing was otherwise well-documented; it did not require validation. His efforts to correlate results were simply a method of ensuring that the use of IHC for ER and PR was accepted by local surgeons and oncologists, some of whom at times proved reluctant to accept any change in a testing method with which they were already familiar.

The issue of standardized reporting of ER and PR results using IHC was also further investigated. In January 1998, Dr. Khalifa presented a document to his local pathologist colleagues entitled “Proposal for uniform reporting of ER/PR immunohistochemical assessment, January

⁷ Transcript of testimony, Dr. Mahmoud Khalifa, July 24, 2008, pp. 118-120.

1998." This draft proposal, which was later finalized, suggested a three-part approach be used for reporting IHC results. By this time, it had been generally agreed that the biochemical assay would shortly no longer be performed for ER and PR, and individual pathologists would henceforth report the results of ER and PR by IHC. The draft proposal was that reports for ER and PR would state whether the ER and PR results were "negative" or "positive," and where they were "positive," a percentage of positivity would also be given. It was proposed that reports would sometimes contain a rider, the wording of which Dr. Khalifa had developed. The rider would be included only when the ER test result was between one and thirty percent positive, and referred to a published paper that correlated such ER IHC results with a negative result in the biochemical assay. While the rider made such a correlation, Dr. Khalifa himself understood that a staining of one percent or greater was a "positive" hormone receptor result. Inclusion of the rider in pathology ER/PR reports was in his view a recommendation only, as pathologists understood they were free to omit it should they choose to do so. The proposed rider read as follows: "Comment: Evidence from the available literature indicates that estrogen receptors immuno-reactivity detected in less than 30% neoplastic cells would most likely correspond to a negative result in a biochemical assay of the same specimen."⁸

Since the pathologists at St. Clare's as a group proportionately dealt with a greater number of breast cancer cases and were therefore relatively more involved in breast pathology than most of their provincial pathology colleagues, they wanted to interpret and report ER and PR for their own cases. Pathologists at the Grace also said that their preference was to interpret their own cases. Dr. Khalifa agreed, and it was at this time that he circulated a February 16, 1998, memorandum to that effect, with the proposal for reporting set out above, to all pathologists in Newfoundland and Labrador. Beginning in March 1998, ER and PR slides were to be sent back for reporting to the pathologist who originally sent the tissue block to the General Hospital for preparation of ER and PR slides. The attending pathologist would choose the paraffin block and send it to the General Hospital, where the ER and PR slides would be produced, and those slides would then be returned to

⁸ Exhibits P-2414 and P-2415; (AM J Surg Pathol 14:121-127, 1990).

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the requesting pathologist for review and reporting. Discussion occurred around how to standardize reporting of the ER/PR test results, the external positive controls that were being used, and the logistics of transporting the slides. Since IHC had locally already been in use for other antibodies, the only novel aspect to ER/PR IHC testing was that it involved an antibody that stained nuclei⁹; all other IHC antibodies used in the province to that point involved cytoplasmic staining.¹⁰ Dr. Khalifa's February 16, 1998, memorandum instructed pathologists to look for nuclei staining; later reminders were required about the necessity of pathologists ordering ER/PR tests for all breast cancer cases. Dr. Khalifa was confident by that time that everyone "knew what ER/PR [was] about." While the group of pathologists then at St. Clare's felt confident enough to begin reading ER and PR slides without further training, those at the Grace requested and received from Dr. Khalifa a package of samples of ER/PR case slides as examples to allow them to determine whether or not they would be comfortable in reporting ER and PR. Dr. Khalifa did not receive any further requests for such sample cases, and was not aware of any concerns ever being expressed about pathologists throughout the province receiving and reporting the ER and PR slides.

Despite the agreement at a January 8, 1998, meeting of Healthcare site chiefs and divisional managers of anatomical pathology that the biochemical assay would no longer be used for ER and PR testing, a transition period did occur. The biochemical assay was still being used for ER and PR testing until some time shortly after March 1, 1998. Dr. Khalifa's February 16, 1998 memorandum to all pathologists in the province¹¹ explained the process that had occurred throughout 1997 to introduce IHC testing for ER and PR. He noted that until that time he had

⁹ Nucleus - "1. the central core of a body or object. 2. cell nucleus: a spheroid body within a eukaryotic cell, separated from the cytoplasm by the nuclear envelope (which is penetrated by pores to allow communication with the cytoplasm), and containing chromatin, a nucleolus or nucleoli, and nucleoplasm. In the nucleus the cell's genetic information is stored on the chromosomes and RNA transcription and processing occur" (*Dorland's*).

¹⁰ Cytoplasm - "the protoplasm of a cell exclusive of that of the nucleus; it consists of a continuous aqueous solution (cytosol) and the organelles and inclusions suspended in it and is the site of most of the chemical activities of the cell. Cf. nucleoplasm" (*Dorland's*).

¹¹ Exhibit P-1850.

been reporting all ER/PR cases for consistency, and that all pathologists were being asked to report the results of their own cases as of March 1, 1998. Attached to the memo was the proposal for uniform reporting. Dr. Khalifa testified that while he did not have any authority to implement province-wide policy or require other pathologists to use this standard of reporting, his suggestion would ensure ER and PR test reports would be consistent and comparable throughout the province, thus making it easier for oncologists and other clinicians to read these reports without confusion. Dr. Khalifa requested feedback on the proposal, but did not receive any. Subsequent to the discontinuance of the biochemical assay, reminders were occasionally required to be given to pathologists about the necessity of their ordering ER/PR tests for all breast cancer patients.

Dr. Khalifa throughout his time in St. John's "[tried] to get the word out" about the importance of ER and PR testing; he gave a lecture on the topic in March 1997 to residents, pathologists, oncologists, breast surgeons, and others. However, he understood that not everyone recognized the importance of the test, or its "delicacy" and its "clinical consequences."¹² Dr. Khalifa in his testimony highlighted the importance of ER/PR testing, pointing out the aspects of diagnosis, prognostic value, and therapeutic influence associated with it. Dr. Khalifa was clearly aware that proper handling of tissue specimens was "absolutely critical"¹³ for accurate results in IHC testing.

After becoming the General Hospital site chief in 1996, Dr. Khalifa did identify areas within the laboratory that needed improvement. Those areas included standardization of pathology reports and of requests for special stains, laboratory policies, and administration. He acknowledged that quality assurance "needed some work," and one of his immediate goals was "to tighten up quality assurance a little bit."¹⁴ He noted that while quality assurance needed to be a department on its own, during his time in St. John's no "full-fledged" quality assurance program existed.¹⁵ There was also no external proficiency testing, and no standard operating

¹² Transcript of testimony, Dr. Mahmoud Khalifa, July 24, 2008, pp. 100-101; p. 104.

¹³ Transcript of testimony, Dr. Mahmoud Khalifa, July 24, 2008, p. 26.

¹⁴ Transcript of testimony, Dr. Mahmoud Khalifa, July 24, 2008, p. 32.

¹⁵ Transcript of testimony, Dr. Mahmoud Khalifa, July 24, 2008, pp. 219-220.

procedures (SOPs) existed in the laboratory. Dr. Khalifa felt that it was not his job to write such SOPs; furthermore, he did not believe himself qualified to train laboratory technologists.

Dr. Khalifa left the province in June 1999. Prior to leaving, he prepared a summary of the work he performed in his various roles, and summarized the pathology workload at various hospital sites within the Healthcare. No one performed an exit interview with Dr. Khalifa, and he was not debriefed prior to his departure from St. John's. In particular, no one spoke with him about the assurance he had given in his February 16, 1998, memo to pathologists throughout the province that patient ER and PR slides would not be sent out to them for reporting unless Dr. Khalifa, who would still be responsible for reviewing the external positive control slides at the General Hospital laboratory, was first satisfied the control slides had adequately stained.

ER/PR and the IHC Service after Dr. Khalifa's Departure

After Dr. Khalifa's departure from St. John's in mid 1999, the IHC section of the General Hospital laboratory became the responsibility of his successor as General Hospital pathology site chief. For an initial period of about one year that was Dr. Patricia Wadden. In early 2001, she was replaced as interim site chief by Dr. Sushil Parai, who then held that position until March 2005.

Dr. Parai testified that he actually had minimal involvement in overseeing the IHC service at the General Hospital. The IHC technologists during his early years as site chief dealt with individual pathologists to address any problems that arose on a case-by-case basis. As site chief he would generally check the ER and PR external positive control slides. In his absence, the pathologist who happened to be on call would do so. He testified that he knew of no written record having been kept that the external positive control slides had properly stained.

During the period between Dr. Khalifa's departure in 1999 and Dr. Gershon Ejeckam's arrival in St. John's in late 2002, concerns were occasionally recorded in writing about problems involving ER/PR

testing. The minutes of meetings of the site chiefs and divisional managers of the pathology laboratory program in early 2001 refer to an ongoing survey as to the quality of immunostains. It found that pathologists were satisfied with the immunostains generally, but in April 2001 concerns were noted about the ER and PR stains due to "some problems with the estrogen and progesterone receptors."¹⁶ Dr. Parai testified that he could not recall there being much in the way of an investigation of the reason(s) for the ER and PR problems other than that the external controls for ER and PR were monitored for a period until people were satisfied the stains were working well. The problem, Dr. Parai recalled, related to whether the ER and PR stains being produced were actually weak positive or positive results.

The minutes of Healthcare's meeting of pathology site chiefs and divisional managers in June 2001 referred to a "Quality Assurance for Anatomical Pathology, Pathologist Review" having noted that a committee to conduct pathology report reviews by system (i.e., breast cancer, colon cancer, etc.) was not then in place.¹⁷ Efforts were subsequently pursued within Healthcare to develop such a program, which efforts continued for years. Dr. Parai explained that they went through at least four or five drafts of such a program. Each draft was circulated to pathologists at both St. Clare's and the General Hospital, as well as to the laboratory managers, all of whom provided feedback that led to further revisions.

Dr. Parai testified that early in his tenure as site chief, Healthcare had a copy of the College of American Pathologists guidelines, but it was such a "very big program" involving a "lot of resources, lot of manpower and funding to implement" that it never was adopted by Healthcare.¹⁸ Efforts continued locally over the years to develop a modified program. At the end of 2004, a draft version was passed over to Dr. Beverley Carter, a pathologist, who had just then been appointed chair of a new quality assurance program.

¹⁶ Exhibit P-1876.

¹⁷ Exhibit P-1877.

¹⁸ Transcript of testimony, Dr. Sushil Parai, July 25, 2008, pp. 327-328.

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Interestingly, during the June 2001 meeting of Healthcare's pathology site chiefs and managers meeting mentioned earlier, there was a discussion of the importance of using standard specimen grossing and reporting in relation to breast cancer. Dr. Parai explained that at that time, new standardized grossing and reporting systems for breast cancer were being implemented in major Canadian medical centres, which systems Healthcare recognized should be adopted locally. Dr. Parai could not recall whether such standard guidelines were ever circulated at the General Hospital. Whether they were or not, the Healthcare pathology reports provided to the Commission for the period 1997 to 2005 show that local pathologists never did uniformly adopt or consistently use standard guidelines when they reported the pathology of breast cancer cases. Dr. Parai acknowledged that even convincing the pathologists at the General Hospital to follow a uniform approach to documenting intradepartmental consultations took years to accomplish.

Dr. Parai believed that the anatomical pathology division of Healthcare during his tenure as General Hospital site chief was "going along on par with the other labs in the country,"¹⁹ including, in his view, laboratories in Ontario, Alberta, and Nova Scotia. He felt Healthcare was ahead of many other hospitals in relation to anatomical pathology. This was so despite his recognition as early as 2001 of the need for a quality control manager for the pathology laboratory, a position never created, because of lack of funding.

Dr. Gershon Ejeckam

Dr. Gershon Ejeckam had both expertise and an interest in IHC when he arrived at the General Hospital in the fall of 2002. By early 2003 he had become involved in the technical operations of the IHC laboratory, and was recognized locally as a "go to" person for IHC.²⁰

During the late fall of 2002 and early winter of 2003, Dr. Ejeckam and other Healthcare pathologists reached the conclusion that some of the IHC slides they were receiving from the laboratory were not interpretable. As a result of those discussions, on April 4, 2003, Dr.

¹⁹ Transcript of testimony, Dr. Sushil Parai, July 25, 2008, p. 338.

²⁰ Exhibit P-0067.

Ejeckam sent a memorandum to pathologists at the General Hospital, St. Clare's and hospitals outside St. John's, noting that immunohistochemical stains for eight antibodies, including ER and PR, "have remained unreliable, erratic, and therefore unhelpful for diagnostic purposes." He said he was halting staining with those antibodies "until we can solve the reliability, sensitivity and specificity problems."²¹ The IHC laboratory continued to produce slides for other antibodies, but for four weeks no requests for staining in relation to the ER and PR antibodies were processed by the laboratory. There was some question as to whether this memorandum was received by pathologists outside St. John's. Dr. Kweku Dankwa (St. Anthony), Dr. Barry Gallagher (Gander), and Dr. Paul Neil (Corner Brook), testified that they did not receive this memo, while other pathologists testified either that they could not recall whether they received it or that they probably did receive the memo.²² Dr. Ejeckam testified that in 2003 he did not feel the need to consult or directly involve Dr. Donald Cook, as Clinical Chief, or Dr. Robert Williams, as Vice-President of Medical Services, because this was a laboratory issue that could be handled within the laboratory.

The problems observed with ER and PR results in 2003 included cytoplasmic staining and irregular (non-reproducible) results. Dr. Ejeckam worked with Ms. Mary Butler, a laboratory technologist, to adjust protocols in an attempt to resolve the problems he and his colleagues had observed. Starting with the ER and PR stains, Dr. Ejeckam identified new positive control tissues, then varied the times used for antigen retrieval and adjusted the dilutions of primary and secondary antibodies. Technical assistance was also sought from DAKO. Ms. Butler sent information to DAKO, and a reply was received on April 22, 2003, in which DAKO suggested that variability in results was related to variability in tissue preparation throughout the province. DAKO recommended the creation and implementation of guidelines for fixation (10% neutral buffered formalin for 18-24 hours). An additional DAKO suggestion was the use of a different antigen retrieval solution and a

²¹ Exhibit P-0113.

²² Transcript of testimony, Dr. Kweku Dankwa, July 11, 2008, p. 218; Transcript of testimony, Dr. Paul Neil, July 10, 2008, pp. 131-132; Transcript of testimony, Dr. Barry Gallagher, July 25, 2008, pp. 85-86.

different detection system. The antibody dilution was changed, as a result of the work of Dr. Ejeckam and Ms. Butler, from a 1:50 dilution of primary antibody to a 1:20 dilution.²³

When Dr. Ejeckam was satisfied that good results were being achieved for ER and PR, he reinstated ER and PR staining. He sent out a memorandum dated May 2, 2003, addressed to the same intended recipients as his April 4, 2003, memo. It informed pathologists that the ER and PR immunostains were being resumed. Dr. Ejeckam testified that the quality of slides being produced after ER/PR testing was reinstated was “as good as anywhere else.”²⁴ In his May 2, 2003, memo, Dr. Ejeckam pointed out how important proper fixation was in achieving accurate results for ER and PR, and suggested that tissue be fixed in 10% neutral buffered formalin for 18-24 hours. He asked that it be noted on requests for ER and PR staining if a fixative other than that recommended was used by the institution requesting the stain. He also advised pathologists to ensure that the pH of the formalin used by their hospital was checked regularly, and that the graded alcohols in tissue processors were changed regularly to ensure that tissue was properly dehydrated. This May 2, 2003, memorandum documents the first written communication to pathologists in the province addressing the use of normal breast tissue as an internal control. Some pathologists testified that they received this memorandum,²⁵ others that they did not.²⁶

Reporting of ER and PR results was also addressed in the May 2, 2003, memorandum. Dr. Ejeckam discussed the variety of reporting methods referenced in the literature, and highlighted the Consensus Statement on Adjuvant Therapy for Breast Cancer that was published by the National Institutes of Health in 2000. He said that Consensus Statement considers any positive nuclear ER staining to be a positive result and a basis for providing anti-estrogen therapy. Dr. Ejeckam also stated in this memo that:

²³ Exhibit P-2177.

²⁴ Transcript of testimony, Dr. Gershon Ejeckam, June 3, 2008, p. 234.

²⁵ Transcript of testimony, Dr. Paul Neil, July 10, 2008, p. 132; Transcript of testimony, Dr. Gary Baker, September 5, 2008, p. 108.

²⁶ Transcript of testimony, Dr. Kweku Dankwa, July 11, 2008, p. 219; Transcript of testimony, Dr. Maurice Dalton, July 18, 2008, p. 222.

- higher staining intensity does not reflect better results;
- all cytoplasmic staining in ER and PR are considered negative results;
- ER positive tumours include:
 - Tubular
 - Mucinous
 - Papillary
 - Ductal (low nuclear grade)
- Low nuclear grade tumours are usually positive for ER/PR, while high grade tumours tend to be negative for ER/PR.²⁷

On June 19, 2003, Dr. Ejeckam sent a third memorandum, which was addressed to Mr. Terry Gulliver and copied to Dr. Desmond Robb (Discipline Chair of Laboratory Medicine), Dr. Donald Cook (Clinical Chief and Site Chief, St. Clare's), and Dr. Sushil Parai (Site Chief, Health Sciences Centre), as well as to Mr. Barry Dyer (Manager, Histopathology). Dr. Ejeckam noted that while the problems with the results of immunostains seemed to have been fixed, the "state of immuno stain at the General Hospital Department of Laboratory Medicine and Pathology is still unsatisfactory."²⁸ He went on to describe the problems he saw with the laboratory, including its physical location (he felt IHC stains needed to be performed in a separate room), the need for dedicated staff to perform IHC, and the fact that funding and staffing levels were not adequate. He highlighted the sensitivity of IHC and the importance of IHC results to patient diagnosis. Dr. Ejeckam confirmed in his testimony that he realized, after working to improve IHC results following his April 4, 2003, memorandum, that optimal conditions could not be achieved given the physical location of the laboratory at that time, the inadequate number of staff, and the lack of dedicated staff performing IHC. He felt it was important to work to improve the situation as much as possible to ensure optimal conditions were reached, particularly since the volume of IHC stains performed continued to increase.

Dr. Ejeckam testified that subsequent to sending out his June 19, 2003, memo, he spoke with Mr. Gulliver about it. He was told Mr.

²⁷ Exhibit P-0113, pp. 3-4.

²⁸ Exhibit P-0113.

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Gulliver expected to act upon it, but he never did hear from him again about it. Dr. Robb and Dr. Cook also spoke with him briefly about this memo. Mr. Gulliver testified that after he received Dr. Ejeckam's June 19 memo, he and Mr. Dyer attempted to address how Dr. Ejeckam's goals could be achieved within the laboratory budget. Separate space for the IHC laboratory became available later in 2003, and when the new Ventana Benchmarks were installed in late 2003, the IHC laboratory moved to its own area. A senior technologist was identified to be trained to perform grossing, allowing the IHC technologists to spend more time on the IHC staining procedure itself.

Approximately one year after Dr. Ejeckam's 2003 intervention in relation to ER and PR slide staining, concerns were again expressed about ER and PR testing. The March 31, 2004, minutes of Healthcare's pathology site chiefs' and divisional managers' March 31, 2004, meeting noted the new Ventana Benchmarks appeared to be "working generally well; however, there continues to be some problems with estrogen and progesterone receptors."²⁹ Witnesses could not recall what the exact concern(s) were at that time.

The General Hospital Laboratory Workload circa 2005

At the General Hospital laboratory, pathology work accounts for approximately ten percent of the laboratory medicine program.³⁰ As of 2005, the laboratory was processing approximately 15,000 IHC slides per year, of which approximately 350 slides were produced to test primary breast tumour tissue for ER and another 350 slides to do the same for PR. Non-primary breast cancer specimens tested for ER and PR status accounted for approximately 10-20 cases per year. Mr. Gulliver testified that the laboratory medicine program in St. John's performs over 10 million tests per year.³¹ IHC is therefore a small percentage of the work done in the laboratory, and ER and PR slide production an even smaller proportion of the total laboratory output.

²⁹ Exhibit P-1913, p. 2.

³⁰ Transcript of testimony, Terry Gulliver, October 8, 2008, p. 101.

³¹ Transcript of testimony, Terry Gulliver, October 7, 2008, p. 330; October 8, 2008, p. 15; and October 24, 2008, p. 334.

Chapter Five

The Aftermath of the “Index” Case

The Aftermath of the “Index” Case

There’s one lobular: could there be more?

Dr. Ford Elms, the same pathologist who read the first ER/PR test for Ms. Peggy Deane in 2002, read the slides on the re-test in 2005. The immunohistochemistry staining for tests in 2002 had been done on a DAKO Autostainer. In 2005, a Ventana Benchmark was used. Dr. Elms interpreted the new slides as ER and PR positive. He called Dr. Stewart Rorke, Ms. Deane’s attending physician during her April 2005 admission, and advised him of the change. Drs. Joy McCarthy, Kara Laing, and Jonathan Greenland, all of whom had been involved in Ms. Deane’s care, told the Deanes, who were pleased to learn that another treatment option was available for Ms. Deane.

Dr. Elms recalled that within 24 hours of talking to Dr. Stewart Rorke he advised the clinical chief, Dr. Donald Cook, of the change in Ms. Deane’s ER/PR status. Dr. Cook’s recollection is that it was Dr. McCarthy who first informed him about the Deane case, probably on May 11, 2005, and shortly after that Dr. Elms also told him about it. It is probable that Dr. Elms’ recollections are correct on this point. While he did not know Ms. Deane personally, Dr. Elms knew who she was and anticipated that Dr. Cook might receive a complaint. He told Dr. Cook that the Deane case was an isolated one, something Dr. Cook would have questioned had he already spoken to Dr. McCarthy about Ms. Deane. No investigation was commenced in the laboratory in the days immediately following the change in Ms. Deane’s ER/PR status.

In the words of Dr. McCarthy, “it took a while for this to sink in.” All of the oncologists at the Cancer Centre knew about Ms. Deane’s case and they discussed it in the following weeks. They wondered if there could be other invasive lobular cases which were incorrectly reported as ER negative. However, the record systems at the Cancer Centre did not readily permit the oncologists to search for all patients with that diagnosis to determine how many had tested ER negative. The oncologists did not think to ask the laboratory whether its records could be used for this purpose.

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The other shoe dropped during the first week of May. On May 4, 2005, Dr. McCarthy saw a patient who had had invasive lobular cancer but who was reported as negative for both ER and PR receptors when tested in 2002. During that visit, the similarity to Ms. Deane's case was not noticed by Dr. McCarthy. On May 6, 2005, Dr. Kara Laing saw another patient for a regularly scheduled follow-up visit. That patient had also had invasive¹ lobular carcinoma and ER/PR negative results reported in 2002. Dr. Laing decided to have that patient re-tested before her return in six months. There was no sense of urgency on May 6. On May 11, Dr. McCarthy's patient returned to the Cancer Centre because of complications with her chemotherapy treatment. Dr. McCarthy began looking for other options for that patient, who wanted to stop chemotherapy. As a result, Dr. McCarthy closely examined her patient's chart. This time, the similarity to the Deane case struck Dr. McCarthy, who decided to have the hormone receptor tests repeated, on an urgent basis.

Dr. McCarthy called Dr. Cook to make that request and during that conversation she also spoke to him about Ms. Deane. Within two days Dr. Cook had completed the re-test requested by Dr. McCarthy and the results had changed from clinically negative to positive. It is probable that in the conversation of May 11, or in one later that week, Dr. Cook was told about Dr. Laing's patient. Dr. Cook's recollections of the events of those few days were not as clear as those of other witnesses who participated. For example, he did not remember that he had interpreted the re-test results for Dr. McCarthy's patient, an event which was critical to the decision to commence a larger re-testing effort. However, Dr. Cook did take notes of certain meetings and conversations in the summer and fall of 2005, which I found to be very helpful to describe the events.

I conclude that the investigation that followed was not triggered by the fact that there had been a change in Ms. Deane's test results *per se*, but by the heightened awareness of the connection between the diagnosis

¹ The terms "invasive" and "infiltrating" are used interchangeably when describing lobular carcinoma.

of infiltrating lobular cancer and the high probability of a positive estrogen receptor. If Ms. Deane had not had infiltrating lobular cancer it is unlikely that she would have been re-tested and, consequently, that the problem would have been discovered in 2005.

On May 17, 2005, Dr. Cook, Dr. Beverley Carter, Dr. Laing, Dr. McCarthy, and Mr. Barry Dyer, Divisional Manager for Anatomical Pathology, met to come up with a plan to resolve the question of whether they were dealing with isolated cases, something that was confined to the time period of Ms. Deane’s testing, or something more widespread. That group decided that there should be an examination of the ER/PR slides done in 2002 and a re-test of those cases where there was a negative ER result. Further, if the number of ER negative cases was not large enough to enable them to draw conclusions based on the re-tests, they might move into 2001. The idea was to treat Ms. Deane’s original test as the centre and move out from there. In addition, at that meeting, the oncologists identified certain additional patients for re-testing. Generally, those patients seem to have been singled out because of a diagnosis of infiltrating lobular carcinoma, or some other diagnosis that was more likely to be associated with a high rate of ER positive results. Those who attended the meeting agreed that if, on re-testing, there were clinically significant changes, the oncologists at the Cancer Centre would inform patients of the Cancer Centre. Other arrangements had to be made for those who had been discharged from the Cancer Centre or who had never been patients of the Centre.

Mr. Dyer² told Mr. Terry Gulliver, the laboratory program director, about the meeting and Dr. Cook advised his immediate supervisor, Dr. Robert Williams, Vice President Quality, Diagnostic and Medical Services, about the meeting and its outcome. On May 24, Dr. Cook summarized in a letter to Dr. Williams what had happened. By that date the ER results for Dr. Laing’s patient had also changed from negative to positive.

² Mr. Dyer recalled that, at the meeting, at least one oncologist was attributing the problem to the work of the technologists.

The Group

Although there appears to have been no formal decision to form a committee to deal with the ER/PR problem, one did evolve. Dr. Williams headed the committee until his retirement in September 2006. Given the nature of the problem and the fact that at the time the Laboratory Medicine Program reported to him, Dr. Williams was the most appropriate person to take the lead. Dr. Williams' title would suggest that the Quality Department also reported to him. That was part of the plan for reorganization on the formation of Eastern Health in April 2005 but Dr. Williams recalled that it was not until "about September" 2005 that Ms. Heather Predham, Acting Director of Quality and System Improvement, began to report to him. However, when Dr. Williams retired, Quality and Risk Management was transferred to the portfolio of the Chief Operating Officer (Children and Women's Health Program) and Ms. Predham began reporting to Ms. Patricia Pilgrim rather than Dr. Williams' replacement, Dr. Oscar Howell.

Dr. Williams, Dr. Cook, Dr. Laing, and Ms. Predham were members of a core group (the Core Group) dealing with the problem.³ These four people, along with others, comprised a larger group (the Group), which also met regularly on the issue. In addition to those in the Core Group, the Group included Ms. Susan Bonnell, who was then the Director, Strategic Communications for Eastern Health, and sometimes with her or in her stead, Ms. Deborah Pennell,⁴ also of Strategic Communications, Dr. Alan Kwan, a surgeon, Dr. McCarthy, Mr. Gulliver, and Mr. Dyer. Dr. Paul Gardiner, Medical Director of the Newfoundland

³ Ms. Predham believed that Mr. Gulliver was a member of the Core Group. I have not included him in that group because, while he was heavily involved in identification of patients and the organization of the St. John's blocks for transportation to Mount Sinai, he had little, if any, involvement in the decisions regarding communications with the patients, other regional health authorities, the public, or Government, after the blocks were sent.

⁴ Ms. Deborah Pennell testified before the Commission. Her name has been Deborah Thomas or Deborah Thomas-Pennell. In this report, these three names represent the same individual.

Cancer and Treatment Research Foundation,⁵ also attended some of those meetings. Four other persons--Mr. George Tilley, Chief Executive Officer of Eastern Health; Mr. Dan Boone, solicitor for Healthcare Insurance Reciprocal of Canada (HIROC); Dr. Al Felix, a surgeon; and Ms. Pat Pilgrim, Chief Operating Officer responsible for the Cancer Care Program --would attend meetings of the Group sporadically.

No minutes were kept of the meetings of either the Core Group or the Group. This is in sharp contrast to the practice of established formal committees at Eastern Health, which use agendas and record minutes describing individuals being charged with taking action on issues. Some of those in attendance at meetings of the two groups did take notes. However, the failure to record systematically information and decisions and formally assign tasks for action meant that some members of the Group took positions or conveyed information to others based on assumptions that were inaccurate. For example, Ms. Predham, a member of the Core Group, believed that all patients whose test results had changed from negative to positive during Dr. Carter’s re-tests in June and July 2005 had been informed of the changes during the summer. That was not correct: after those who had changed results in the first group were informed, it was decided to await the re-testing at Mount Sinai Hospital (Mount Sinai) in Toronto before other patients were told about changes in their results.

The members of the Group had no consistent view of the decision-making process. Some described the process as consensus-building. Others saw the decision-maker as Dr. Williams or, on certain issues, Mr. Tilley. On occasion “decisions” made during a meeting of the Group or the Core Group would be recorded by Dr. Williams in the form of a letter to the person who might have been asked to follow up on some point. However, the letter might not record the decision as having been made. Rather, Dr. Williams might ask for advice on the point. Further, the letter might also contain another point that had not been discussed at the

⁵ In 2005, the Newfoundland Cancer Treatment and Research Foundation became part of Eastern Health. What is now the Cancer Care Centre, however, continues to provide province-wide services using, in part, facilities at various hospitals throughout Newfoundland and Labrador.

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meeting. An example of this can be found in a letter dated July 29, 2005, from Dr. Williams to Dr. Cook, in which he seeks the advice of Drs. Carter and Cook on several questions, a number of which had already been discussed, and some would say decided, others of which were new. Consequently, it is difficult to be precise about when decisions were made or whether what was ultimately done reflects the decision made during a meeting or events that occurred after the meeting.

Aside from these two groups, there were also meetings of the leadership team of the Laboratory Medicine Program, which included Dr. Williams, Dr. Cook, and Mr. Gulliver, all of whom were actively involved in the ER/PR problem.

Dr. Beverley Carter's Investigation

Manipulate the data ... see if something stood out

The re-testing, which Dr. Cook had agreed with Drs. Laing and McCarthy should be carried out, was to be done in-house using the Ventana Benchmarks. Dr. Cook enlisted the aid of Dr. Beverley Carter, FRCP (C), to try to determine the extent of the problem. In 2004, Dr. Carter had joined the staff of Healthcare as a staff physician, anatomic pathology. The Royal College of Physicians and Surgeons of Canada does not recognize breast pathology as a subspecialty. However, Dr. Carter, having completed a fellowship in Breast Pathology/Molecular Techniques at Vanderbilt University, Nashville, USA, is considered by her colleagues to be a breast pathologist. Her expertise made her the obvious choice for any internal examination of the problem.⁶ The one drawback was that because she had done some locums in St John's in the last half of 2003, her own work might have to be reviewed. However, the initial efforts were to concentrate on 2002, a time period for which any such concern would not apply. Cases that had been read outside St.

⁶ Dr. Ejeckam, who had a special interest in immunohistochemistry, would also have been an appropriate person to lead the internal investigation. There is no indication that he was considered for the task but, in any event, he had planned a holiday from July 18, 2005 to the end of August, and, therefore, would not have been available at a critical time. However, what has never been adequately explained is why during the period from May 17 to July 18, 2005, no one within Eastern Health sought his counsel or attempted to tap his knowledge of past events.

John’s would also be included in her review. At that stage, Dr. Carter’s investigation was not intended to be the definitive work on ER/PR testing. She was to “begin to manipulate the data and see if something stood out.”

Dr. Carter’s review during June and July 2005 included what had been agreed to at the meeting on May 17, which was a re-testing primarily of 2002 cases where there was a negative ER result. While there were communications between Dr. Carter and Dr. McCarthy about individual patients as the work was being done, three letters summarized the results of this aspect of Dr. Carter’s work. The first letter, dated June 29, 2005, lists 25 re-test results. The estrogen receptor status of 16 of those patients changed from clinically negative to positive.

As Dr. Carter did her work, she and Dr. Cook discussed her progress. By mid-July she had identified as having a changed estrogen receptor status the 16 cases listed in her letter to Dr. McCarthy of June 29, 2005, and others that had not yet been officially reported. Further, she was seeing certain trends: “looking at the slides, I could see things like internal controls not staining over a wide variety of those cases leading me to believe that it wasn’t an isolated incident, that that was fairly common.”⁷

It was agreed by Dr. Carter and Dr. Cook that Dr. Carter’s investigation needed to be expanded. Dr. Carter recorded their plan in a letter of July 14, 2005, directed to Dr. Cook, though even before that letter was written she had expanded the scope of her investigation. She wanted to look at the whole of the procedures in the immunohistochemistry laboratory, including the external controls, the policies and procedures, validation and quality assurance. She found that she could not consistently match the external control slides with any particular date, and consequently with any particular case. She also complained that she was having trouble getting information from the technologists. In her letter, Dr. Carter stated that the slides she had then reviewed showed “problems with the technique of estrogen receptor testing and the

⁷ Transcript of testimony, Dr. Beverley Carter, July 29, 2008, p. 53.

interpretation of same.” In other words, she had identified problems in the work of both the technologists and the pathologists.

The examination would now be expanded to all estrogen receptor status tests done in the laboratory from 1997 to 2004, whether positive or negative.⁸ However, priority was to be given to the negative cases. Dr. Carter outlined the work that would be required of others to provide her with what she needed to do and properly record the re-test results. As a quality initiative, ten percent of the re-tests were to go to Dr. Frances O’Malley at Mount Sinai for further testing. Dr. Cook undertook to provide Dr. Carter with the resources necessary to do the work in his reply of July 19, 2005, which he copied to Dr. Williams.

By the end of July 2005, the three letters that Dr. Carter sent to Dr. McCarthy provided the results for 93 patients, 59 of whom had had a clinically significant change in estrogen receptor results. Dr. Carter’s spreadsheets indicate that there were other cases she examined that were not included in those three letters. When she sent 11 cases to Dr. O’Malley for a quality review, Dr. Carter included cases where the original results had been positive.

Dr. Carter was of the view that the resources she had been promised to perform the larger review had not been provided, or at least not on a timely basis. She was particularly concerned that technologists assigned to her project were being diverted to do other work. She asked to attend a meeting of the Group, which was to be held on August 1. Dr. Carter was not a member of the Group, but Mr. Tilley was to attend the meeting and Dr. Carter wanted to make a personal appeal to him for the resources she needed.

There are many different versions of what occurred at the meeting of the Group on August 1. The notes taken by various participants reflect, in part, the interests of the note-taker. Dr. Cook’s recollection was that they talked about the issue of technology, the possibility of technical

⁸ This would cover the period from the commencement of ER/PR testing using immunohistochemistry to the time when Eastern Health stopped using the DAKO Autostainer.

error, the issue of pathology interpretations, the issue of stopping all testing and looking for a centre to handle the re-testing process. With one exception I am satisfied that those subjects and others were discussed. I conclude that the search for another centre to handle testing was, on August 1, confined to the current and future ER/PR testing. At that point the plan was still to do the re-testing in-house.

Dr. Carter asked Mr. Tilley to ensure that she receive the resources she believed she needed to carry out the larger retrospective review. Mr. Tilley was not receptive to this request. Citing the management structure of the organization, Mr. Tilley advised Dr. Carter that she would have to work out her problems regarding resources with Dr. Williams. At that meeting, there was also a heated exchange, primarily between Dr. Carter and Mr. Gulliver, respecting the cause of the ER/PR problem. Mr. Gulliver was taking the position that the increased positivity rate using the Ventana Benchmark was a result of improved technology. It was, in Mr. Gulliver’s opinion, an expected and a good thing. Dr. Carter was firmly of the opinion that improved technology did not explain what had caused the many “conversions” seen to that point. This exchange is relevant to the decisions regarding communication and I shall return to it in that context. However, in an attempt to defuse the tension in the room, Mr. Tilley asked Dr. Laing if there was a possibility that one patient might be helped by the re-testing. Dr. Laing replied “Yes.” Mr. Tilley then declared that nothing else mattered. While this might not have been the first expression of the sentiment, thereafter the mantra of Eastern Health became “we are doing it for our patients.”⁹ That theme perhaps encouraged employees in the long weeks and months of hard work which followed. However, Eastern Health had no real choice; it had to conduct the re-test. Dr. Carter’s work up to August 1 had revealed that there were serious problems with ER/PR testing, ones that would have an influence on the accuracy of future testing whether it was performed with a DAKO Autostainer or a Ventana Benchmark. To continue ER/PR testing without further investigation and resolution of the problems

⁹ In a statement to the media on May 18, 2007, Mr. Tilley echoed this sentiment when he said: “We felt that if there was even the **possibility** that one patient may benefit from retesting, we had an **obligation** to retest all patients, regardless of the consequences” (P-0443, p. 3).

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could perpetuate errors. To fail to re-test for prior years would be knowingly to leave a number of patients with incorrect results, thereby depriving them of a chance of treatment which, the Group had been advised, could be beneficial even years after the initial diagnosis.

Dr. Cook and Dr. Williams, who, by virtue of their positions, were chiefly charged with investigating and addressing the ER/PR problem, knew that it was large, but not yet how large. Dr. Carter had identified certain difficulties with the slides but the investigation of the problem was far from complete when she resigned from the project on August 2, 2005. A new plan had to be developed. Meanwhile, another issue was developing.

The Ventana Benchmarks

Is the Ventana too sensitive?

Generally, within Eastern Health, early on there was an accepted notion that the Ventana Benchmark was more sensitive than the DAKO Autostainer had been. In his first written report to Dr. Williams on May 24, 2005, Dr. Cook said that patients with changed results would be told that the re-test had been done using their “newer more sensitive technique,” which could only refer to the Ventana Benchmark. On July 12, 2005, in notes of a meeting with Dr. Cook, Mr. Gulliver, and Ms. Predham, Dr. Williams records, in respect of the Ventana system, “company says ten times more sensitive.” That information probably came from Mr. Gulliver. Interestingly, by the August 1 meeting, Mr. Gulliver was denying to Ms. Predham that he had said that the Ventana was more sensitive, maintaining that he had said it was more consistent. Ms. Bonnell, however, supported Ms. Predham’s memory of events and said she had a note of Mr. Gulliver having made such a statement. In spite of this change of position by Mr. Gulliver, in October 2005 Ms. Pennell, in commenting about a news report, stated that the reporter should have said that the Ventana was more sensitive, rather than more accurate.

At some point in July, Dr. Carter and others began to question the accuracy of the results from the Ventana Benchmarks. Dr. Carter’s concern was not with the Ventana Benchmarks *per se* but whether other

factors might mean that the Ventana instruments were not performing optimally and, therefore, were producing false positives. Dr. Cook confirmed that Dr. Carter had been afraid that proper validation procedures had not been followed before the Ventana Benchmarks were put into use.¹⁰ A lack of documentation of the validation procedures meant that Dr. Carter was not able to evaluate what had taken place in 2004. However, if Dr. Carter was not concerned with the Ventana Benchmarks *per se*, Dr. Cook’s inquiries on the subject suggest that he was.

There were three prongs to Dr. Cook’s investigation of whether the Ventana instrument was “too sensitive.” First, as noted above, Dr. Carter was sending to Dr. Frances O’Malley at Mount Sinai, as an “outside quality assurance consultation,” a percentage of the blocks she had re-tested. Dr. O’Malley would repeat the ER/PR tests at Mount Sinai and report the results. There would then be a comparison done of the results for the cases that had been re-tested both at Mount Sinai and by Dr. Carter. In addition, Montreal Jewish General, which also used Ventana Benchmarks, was asked to re-test a number of cases.¹¹ Second, Dr. Cook would make inquiries of other laboratories which used the Ventana Benchmark to try to determine their experiences using that instrument. Third, Dr. Cook planned to call Ventana Medical Systems, Inc., in Arizona to discuss the issue with them.

At a meeting of the Group¹² on July 27, 2005, it was decided that the Canadian representative of Ventana Medical Systems would be asked to come to look at the instruments in operation at the General Hospital. Dr. Cook’s notes of that meeting also include the following entries:

¹⁰ Dr. Cook stated that the rate of positives Dr. Carter was getting on the re-tests using the Ventana Benchmarks was 89%. (Exhibit P-0081 would suggest that Dr. Carter found 82.5% positivity when the re-tests were factored in. Dr. Mullen suggests that his rate on the prospective cases [79.2%] was about right for the Newfoundland population.)

¹¹ Because of problems being experienced with the Ventana at the Montreal Jewish General at the time, this comparison was never made.

¹² Ms. Predham, Dr. Kwan, Ms. Bonnell, Mr. Boone, Mr. Gulliver, Dr. Williams, Dr. Cook, Dr. Gardiner, Dr. Laing, and Dr. McCarthy. Drs. Laing and McCarthy participated by phone.

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- await result of Montreal General and Mount Sinai
- go slow.

The first point obviously refers to the comparison tests that were to be being run at the two institutions. The second, Dr. Cook recalled, referred to the question of telling patients about the results of the in-house re-testing being done by Dr. Carter. Dr. McCarthy by that time had received the results for the second batch of re-tests. However, while Dr. McCarthy was the oncologist receiving the results of the re-tests being done by Dr. Carter, she was not personally responsible for informing those patients whose results had changed from clinically negative to clinically positive, unless the patient was considered to be her own patient. If there was a changed result, then an addendum to the patient's pathology report would be produced by a pathologist and entered on the patient's chart. But in addition, copies of addenda to the pathology reports would be sent to Dr. McCarthy, who would ensure that the appropriate physician also received a copy of the addendum. Dr. McCarthy also spoke to the responsible physicians, who were expected to notify their patients.

Most of the first group of 16 whose test results had changed from clinically negative to positive had already been informed by August 1. Dr. Williams recorded on August 2, 2005 that four were already on appropriate treatment, 10 had been advised that they had converted, (presumably) by oncologists or other treating physicians, and two had been advised by surgeons. Nothing was said to those patients whose results were unchanged. It appears that no one from the second and third group was contacted on the basis of the re-tests done by Dr. Carter. Later there would be re-testing at Mount Sinai. The second and third group were included in that re-test and advised of the re-test results. This reflected the doubts as to the reliability of the results produced locally with the Ventana Benchmark at that point.

On July 28, Dr. Cook made a number of phone calls. The information gathered was not definitive. Some of the data he sought, such as the difference between positivity rates before and after a Ventana Benchmark began to be used, was not available for one institution. There

was a comment that the Ventana had high sensitivity, particularly for an antibody used in the Human Epidermal growth factor Receptor 2 (Her2/neu) test. A contact at another institution reported good correlation between the DAKO and Ventana instruments in use at their institution. Dr. Cook also heard accounts from two contacts of problems having been experienced with a DAKO Autostainer.

A Ventana Medical Systems representative was noted by Dr. Cook to have said that the Ventana Benchmark provided less opportunity for human error than the DAKO Autostainer and to have suggested that could be one explanation for the difference in positivity rates. There was also speculation regarding the differences in the antibodies used by Eastern Health with the two instruments.

By July 29, 2005, Drs. Carter and Cook instructed Mr. Dyer to stop all ER/PR testing with the Ventana Benchmark until the matter could be considered more fully. That decision was later confirmed by Dr. Williams. Also on the morning of July 29, the report on 11 cases that had been sent to Mount Sinai was received in St. John’s.

On the morning of August 1, 2005, consistent with his note of July 27, Dr. Cook advised Dr. McCarthy not to report additional ER and PR conversions to patients until after the meeting to be held at 5 p.m. that day. By that afternoon the results of the first 11 cases sent to Mount Sinai were being reported to the Group.¹³ The Mount Sinai results were not completely consistent with the results on the Ventana Benchmarks. Dr. Carter described the Mount Sinai results as being 60% in agreement on ER receptivity. Of the 40% where she found disagreement, 20% were described as serious. She noted that the PR results appeared to be even more problematic. There were five major differences respecting the PR results.

The Group discussed the idea of sending, as a validation exercise for the Ventana Benchmarks, all ER/PR tests to an outside laboratory for

¹³ Attending that day were Mr. Tilley, Dr. Cook, Dr. Williams, Dr. Carter, Dr. Laing, Dr. McCarthy, Dr. Kwan, Mr. Gulliver, Mr. Dyer, Ms. Bonnell, Ms. Pilgrim, and Ms. Predham.

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a period of months. The concept was that slides cut from the same block would be processed both locally and at an outside laboratory. Pathologists at Eastern Health would then read and compare both sets of slides. This plan was to change several times. The IHC laboratory at the General Hospital, as planned, continued to stain the slides in St. John's, but those were not read. The slides produced at Mount Sinai were read in Mount Sinai.

The Canadian Ventana representative was asked to examine the procedure and protocols used for the ER and PR stains done on the Ventana Benchmarks, as well as the knowledge and capacity of the technicians to troubleshoot and run the instruments. Ms. Carole Quevillon completed her report on August 5. Her opinion, which was never questioned by anyone at Eastern Health, was that the instruments were running within specifications, the staining of the instruments was satisfactory, the protocols were consistent with Ventana recommendations and usage in other Canadian labs, the pH of solutions was within specifications, and the technicians were properly trained and able to troubleshoot if there was a problem. The only negative note in her report was that recommended equipment maintenance procedures were not being followed. The Ventana representative's report did not support the view that the Ventana Benchmarks were not operating properly. It did not and could not address the problems with ER/PR testing identified earlier by Dr. Carter. The opinion of Ms. Quevillon related only to the capacity of the technologists to troubleshoot for problems with the instruments. She was not expressing an opinion on the capacity of the technologists to troubleshoot generally for problems with tissue fixation or processing. In any event, by August 5, 2005, the plan to send prospective cases to Mount Sinai was already in place.

For a period in July and early August, members of the Group hoped that it was not so much that the DAKO Autostainer had provided fewer ER positives than it should, but that the Ventana Benchmarks were producing more ER positive results than they should: in effect, that the Ventana was "overcalling" ER/PR results. The hope was that if the Ventana was overcalling, the total number of false results from the earlier testing would be within what was believed to be an acceptable range of

error for the test. Whatever others in the Group might have thought, Drs. Cook, Carter, and Williams knew that observations being made by Dr. Carter reflected badly on the practices being followed by both the technologists and pathologists. They knew that overcalling by the Ventana Benchmarks could not explain the failure to produce a high percentage of ER positive results for infiltrating lobular carcinoma cases. Further, it would not make sense that the false results would be limited to those cases which fell within the relatively narrow category of invasive lobular carcinoma.

Chapter Six

The Re-Testing Effort

The Re-Testing Effort

The Decision to Re-test at Mount Sinai

While there were some discussions with other institutions, Eastern Health very quickly focused on Mount Sinai as the best place to do the re-tests. Mount Sinai had already agreed to do the prospective cases for Eastern Health and the other three regional health authorities. Mount Sinai also used a DAKO semi-automated platform, and was using the 6F11 antibody, which “had been clinically validated by Dr. Allred.” That is, the antibody used for ER testing at Mount Sinai was supported by clinical studies.

Mount Sinai was an excellent choice. First, this meant that the re-testing would be done by a laboratory independent of Eastern Health, one that used a DAKO Autostainer, as had been used in the laboratory at the General Hospital for most of the time period under review, though the antibodies used in the two laboratories were not identical. During the retrospective, Mount Sinai used the 6F11 antibody. Second, Mount Sinai’s laboratories had been through accreditation procedures. In addition, Mount Sinai participated in the UK NEQAS proficiency testing program, as well as one conducted by the College of American Pathologists. Finally, it was doubtful that the laboratory at the General Hospital could cope with the massive amount of work required to complete the large scale re-testing.

The plan for re-testing at Mount Sinai was different from the one originally developed by Dr. Carter. There was to be no comprehensive re-examination of the original slides. The re-testing was to be limited to primary breast carcinoma¹ cases where the estrogen receptor status had originally been determined to be clinically negative, as that was defined at the time the original test was done. Within the St. John’s hospitals of

¹ A relatively small number of other than primary breast cancer cases found their way into those re-tested. In addition, NLCHI identified eighteen cases included in those re-tested, as being clinically positive.

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Eastern Health,² the patients would be identified, the blocks would be pulled by technologists and a pathologist would choose the best block for re-testing. That was most often, but not always, the block from which the original ER and PR slides had been cut. At Mount Sinai, slides would be produced and both estrogen and progesterone receptor status would be reported. The re-test results would be sent electronically, on spreadsheets, to Dr. Cook, who would, for those tests originating in a St. John's hospital, dictate and sign an addendum to the patients' charts based on the figures provided by Mount Sinai. For patients whose blocks had come from hospitals outside St. John's, Dr. Cook would send the information to the other regional health authorities and pathologists from those organizations would add the appropriate addenda to the patients' charts.

On June 14, 2005 Dr. Cook, for the purpose of the work of Dr. Carter, asked the laboratory directors for the other regional health authorities in the province to send their negative ER and PR cases for 2002 to Mr. Dyer at the General Hospital. Dr. Cook did not define negative. A memo of September 6, 2005, directed to the same laboratory directors, addressed two points: what was to be done with the prospective cases and the new plan for a larger re-test to be carried out at Mount Sinai. As to the first, Dr. Cook advised that Eastern Health would not be reporting on estrogen or progesterone receptors in the immediate future. That question would be reviewed after certain events, including the reports from "medical and technical consultants." As to the second, he asked that all ER negative cases on primary breast lesions, independent of PR status, from May 1997 to March 31, 2004 be forwarded to Mr. Dyer. He added the following details:

From January 1, 2001, ER negative is defined as 10% or less. From May, 1997, to December, 2000, ER negative is defined as 30% or less.³

² On the formation of Eastern Health, the hospitals at Clarenville and Carbonear became part of Eastern Health, though when the testing was done they were parts of other organizations. For this purpose Carbonear was treated as a separate region, and Dr. Baker prepared and signed any addenda to reports made necessary by the re-testing. Dr. Ahmad did the same in Clarenville.

³ Dr. Cook's memo was based in part on Dr. Khalifa's original memo to pathologists. In practice positive was 10% or more or 30% or more depending on the time frame.

I would ask that you submit the pathology report, original ER and PR slides, including any controls, as well as the H & E slide and paraffin block of the tumour. We will forward these ER negative cases to Mount Sinai for re-testing.

All ER's and PR's performed on the Ventana System from April 1, 2004 to August 9, 2005, will also be referred to Mount Sinai for retesting. You can forward these cases to Mr. Barry Dyer.

I would like to emphasize at this particular point in time that you concentrate on the 1999 to 2004 years, followed by the 1997 to 1998 years, and then the April 1, 2004, to August 9, 2005 year.⁴

As is evident, for those whose ER test had been done using the DAKO Autostainer, whether there would be a re-test was determined by ER status, while all ER and PR tests done using the Ventana Benchmark were to be re-tested, whatever the original result. Clearly, doubts about the results from the Ventana Benchmark continued to exist.

In the days before September 6, 2005 Dr. Cook had called the laboratory directors for the other regional health authorities to tell them this memo was coming. What was being asked of them turned out to be an enormous task, as indeed it was for the St. John's hospitals. It should be noted that there were differences in the written instructions given to the other regional health authorities and the information given to St. John's pathologists by Dr. Cook on August 8, 2005. The August 8 memo, when referring to the ER negative cases from May 1997 to March 31, 2004, stated that the cases of deceased patients would not be included in those sent. Further, ER negative was defined as "10% or less." Where it was known that the patient was deceased, St. John's would put the blocks for that patient aside, but two of the other regional health authorities, the Central Regional Integrated Health Authority and the Labrador-Grenfell Regional Integrated Health Authority, would include those blocks in those sent for re-testing. As a result, a number of blocks for deceased patients were forwarded to Mount Sinai. As to the definition of negative, whatever the August 8 memo had said, like the other regional health authorities, Eastern Health varied the percentage used, depending on the year the blocks were produced.

⁴ Exhibit P-0590.

Dr. Cook's choice of January 1, 2001, as the date that ER negative would be defined as 10% or less, rather than the 30% or less which had been established by Dr. Khalifa, would turn out to be problematic.

The "Weak Positives": Daphne Coffin

The criterion used by Eastern Health in 2005 to identify patients eligible for re-testing was ER positivity of 30% or less for specimens originally tested prior to January 1, 2001 and thereafter 10% or less. Dr. Cook testified that this was his understanding of the cut-offs used by oncologists and that was based on information provided to him by Dr. Laing. On August 8, 2005, Dr. Cook sent a memo to all anatomical pathologists in St. John's as well as Dr. Williams, Mr. Gulliver and Mr. Dyer. In that memo he advised of the re-testing process and stated the review would pertain to all cases that were ER negative on the primary breast lesion independent of PR status, "ER negative being defined as 10% or less."⁵ His handwritten notes on this memo, however, indicate that on August 10, 2005 he had a discussion with Dr. Laing regarding cut-off points. He writes, "Jan. 2001 onwards, oncology decision to use 10% as cutoff." Dr. Cook admitted however, that this was not "hard and fast"; there could be variation in cut-offs used by individual oncologists but this was "sort of" a cut-off point they were using.⁶

Dr. Laing acknowledged that there was no consensus amongst oncologists that as of January 1, 2001 they would all use a 10% cut-off. In fact, she believes there were oncologists using a 30% cut-off well into 2002.⁷ Dr. Laing contended that any information she gave to Dr. Cook would have been with respect to her own practice only and not that of all medical oncologists. In 2005 when discussing this issue with Dr. Cook, she had not consulted her colleagues to determine when they had adopted 10% as a cut-off for positivity. There was no evidence of any formal communication amongst treating physicians as to the change in the cut-off nor was there anything distributed in writing that stipulated

⁵ Exhibit P-0942.

⁶ Transcript of testimony, Dr. Donald Cook, July 4, 2008, pp. 97-101.

⁷ Transcript of testimony, Dr. Kara Laing, September 9, 2008, p. 139.

that as of January 1, 2001 the accepted cut-off would be 10%. Dr. Laing was aware, however, of the cut-offs chosen to identify patients for re-testing and while she contended that she was not part of the final decision in that regard, she also did not express any concern as to the criteria.

Ms. Predham's testimony differed from that of Drs. Cook and Laing on this point. She testified that she was present for "at least" three conversations between Dr. Cook and Dr. Laing when the issue of cut-offs was discussed and it was very clear to her that it would be safe to use a 10% cut-off as of January 1, 2001.

CHAYTOR, Q.C.:

Q. And so in what you overheard, did you feel it safe to use the two different cut offs for the dates that were provided by the oncologists?

MS. PREDHAM:

A. Yes, it was very clear and it was being cautious, I guess, is a term I'm looking for. You know, that we use 30 percent to the end of 2000 and after that point, you would get ten percent, because a lot of people used ten percent before then, but just on the off chance that you had some.

CHAYTOR, Q.C.:

Q. Okay. So you never heard Dr. Laing express any reservation around that?

MS. PREDHAM:

A. Absolutely not.

...

THE COMMISSIONER:

Q. So do I take it from that, you understood that at the outside, by the commencement of 2001, all oncologists would have moved to using ten percent positivity?

MS. PREDHAM:

A. That's what I understood.

THE COMMISSIONER:

Q. While some may have done it before that, by beginning of 2001, they would have all made the move?

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MS. PREDHAM:

A. Yes.⁸

It is apparent that not all treating physicians used the same clinical definition of positivity at the same time. Nonetheless, Dr. Cook testified that there was no consideration given to utilizing a 30% cut-off for the entire re-testing period.⁹ Dr. Cook's memo of September 6, 2005, which was circulated to all laboratory directors throughout the province, stipulated that for the purposes of identifying patients for re-testing, "from January 1, 2001 ER negative is defined as 10% or less. From May, 1997, to December, 2000, ER negative is defined as 30% or less."¹⁰ Using this nebulous criterion to identify patients who may not have received hormonal therapy in the past, created a risk that patients were overlooked for re-testing.

Furthermore, there could well be patients who were weakly positive on their original test, and having weighed all of the risks and benefits of hormonal therapy decided against it. Some of those patients might well have chosen the treatment if they had received a strongly positive result.

Ms. Daphne Coffin, a retired ultrasound technologist of Eastern Health, was originally a "weak positive" patient. Ms. Coffin was diagnosed with breast cancer in St. John's on August 2001. At the time of diagnosis she was informed by her oncologist, Dr. Laing, that her hormone receptors were ER positive at 23% and therefore she would not be a strong candidate for tamoxifen. The addendum to her pathology report records ER 23% positivity, PR negative, and then in brackets the words "no controls." Notwithstanding the reference to "no controls," the results of the ER/PR tests were reported and relied upon by her treating oncologist.

⁸ Transcript of testimony, Heather Predham, October 17, 2008, pp. 160-163.

⁹ Transcript of testimony, Dr. Donald Cook, July 4, 2005, p. 101.

¹⁰ Exhibit P-0590.

Ms. Coffin recalled that on her October 19, 2001 visit, Dr. Laing explained to her that 20% was considered negative. Based on her low ER positivity level and the side effects of tamoxifen, Ms. Coffin and Dr. Laing decided against hormonal therapy. Had she been ER positive, the initial plan was indicated to be to start her on tamoxifen without chemotherapy.¹¹ Ms. Coffin underwent a course of radiation and chemotherapy. Having completed chemotherapy, she was seen by Dr. Laing on January 28, 2002 for discussion regarding tamoxifen. Dr. Laing's Progress Note for that date states, "her initial tumour was only 23 percent positive for estrogen. In some labs, this is considered to be negative if it is less than 30 percent staining. I would consider this to be a borderline result."¹² The benefits and risks of tamoxifen are discussed and the decision was reached not to use tamoxifen.

Ms. Coffin was seen by Dr. Laing on September 8, 2005. The Progress Note of that date refers to Ms. Coffin being ER "weakly positive" and PR negative. The plan was to see her in the spring of 2006 and, if all was well, she was to be discharged. There was no mention to her during this meeting that there was re-testing occurring of ER/PR specimens.

In October 2005, when this issue broke in the media, Ms. Coffin was not in the province. She learned in January 2006 about the re-testing while attending a breast cancer support group meeting. As a result, she contacted the Cancer Centre, identified herself and asked to be put on the list for re-testing.

She heard nothing further. On March 14, 2006, she attended what was supposed to be her last appointment with Dr. Laing prior to being discharged. At that appointment, Dr. Laing asked Ms. Coffin about the outcome of her re-test stating, that anyone with an ER less than 30% had been re-tested. Ms. Coffin responded that to the best of her knowledge she had not been re-tested notwithstanding her efforts to have herself re-tested. Dr. Laing's Progress Note for that visit states, "I had thought that she would be retested as her staining was less than 30% but this has not

¹¹ Exhibit C-0058; Progress Note – Dr. Jonathan Greenland, September 19, 2001.

¹² Exhibit C-0062.

been done.”¹³ Dr. Laing confirmed this by review of Ms. Coffin’s chart and promptly arranged to have her sample re-tested. No explanation was offered to Ms. Coffin as to why she was missed in the original identification of patients in 2005-2006 and she felt Dr. Laing was genuinely surprised that she had been missed since all patients with an ER positivity under 30% were supposed to have been re-tested. Upon realizing Ms. Coffin had not been re-tested, Dr. Laing did not see the need to alert Dr. Cook or anyone else to the possibility that other “weak positive” patients may have been missed because she did not consider Ms. Coffin to be a patient that was overlooked because of the cut-off criterion. Furthermore, no memo, email, or other direction was given to other oncologists to review their charts to see if any of their patients might fall into the same category as Ms. Coffin.

The re-test at Mount Sinai was carried out on March 17, 2006 and found Ms. Coffin to be 95% ER positive. This result was entered on her chart on March 21, 2006. The plan on March 14, 2006 had been that Dr. Laing would arrange the re-test and call Ms. Coffin with the results.¹⁴ It would be almost six months later, however, before the changed result was communicated to Ms. Coffin.

In May 2006, while attending a breast cancer retreat, Ms. Coffin spoke with a nurse from the Cancer Centre and asked her to check if her re-test had been carried out. The nurse promised she would do so. Ms. Coffin was asked to come to the Cancer Clinic on September 6, 2006 and was advised by Dr. Laing of the result of her re-test. The Progress Note for that day states, “I brought her back today to discuss the issue of her ER again. She had not been retested despite the fact that she was less than 30 percent, but now that she has been and it came back so strongly positive, she comes to talk about late hormonal therapy.”¹⁵ Ms. Coffin was offered and commenced hormonal therapy. She was not told that her re-test had in fact been carried out some six months earlier nor has she ever been offered any explanation as to why this delay in communication occurred. In fact, Ms. Coffin first learned of the delay in communicating

¹³ Exhibit C-0067.

¹⁴ Exhibit C-0067, p. 2.

¹⁵ Exhibit C-0068.

the re-test results with her during her interview with Commission Counsel in 2008.

Dr. Laing acknowledged that it was because of Ms. Coffin's own initiation of further contact with Eastern Health on this issue that her case was once again drawn to Dr. Laing's attention. Ms. Coffin's results had come back from Mount Sinai and were placed on her chart without having been brought to Dr. Laing's attention. In this case, although Dr. Laing had ordered the consult, she testified that neither the final surgical pathology report nor the supplementary pathology report was brought to her attention. Dr. Laing testified that while the latter document contains her initials and those of another physician, it had been brought to the other physician's attention and filed in Ms. Coffin's chart without having first been brought to her attention. Up to September 10, 2008, when Dr. Laing testified regarding this issue, no policy or procedure had been established by the Cancer Care Program to ensure treating physicians receive all pertinent documentation concerning their patients. This needs to be addressed.

Ms. Coffin does not believe her decision in 2001 to not take tamoxifen would have been any different if she had been told the cut-off for positivity at the time was 10%. However, had she been told she was 95% positive, her decision would indeed have been different.

Dr. Laing testified that Eastern Health had contacted Dr. Maureen Trudeau, an oncologist from Sunnybrook Hospital in Toronto, in April 2008 on the issue of whether to re-test the people who may have been missed due to the uncertainty of the changeover date from 30% to 10%. According to Dr. Laing the consensus at the end of the discussion with Dr. Trudeau was that it would be worthwhile to try to identify these patients. On September 12, 2008, after the conclusion of Dr. Laing's evidence, counsel for Eastern Health emailed Commission Counsel to advise as follows:

The consultation with Dr. Maureen Trudeau that Dr. Laing spoke of was initiated following the evidence of Ms. Coffin. Her case raised the issue of whether there might be other cases where a change from weak positive to strong positive would have influenced the decision to take hormonal therapy or

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not. Pat Pilgrim has informed me a decision has recently been made to not to pursue the database initiative that had been considered with Wayne Miller and that Dr. Laing spoke of. That decision had not been communicated to Dr. Laing before she gave evidence. The overall question of the weak positives has not yet been fully resolved.

Contrary to Dr. Laing's recollection, the consultation was not about whether the correct cut off for clinical negatives had been selected. The cut off date had been selected in 2005 by consultation between pathology and oncology. See for example volume 58 page 81 where Dr. Cook noted confirming that date with Dr. Laing. Heather Predham will also say that she was present when Dr. Cook [and] [sic] Dr. Laing discussed it. **Whether January 1, 2001 was the right date for the change in retesting selection criteria has not been re-examined, since there has been no prior indication from any clinician that it was not correct. This is now, however, a source of serious concern and will be investigated further to see if any action is required.** [emphasis added]

Dr. Cook had acknowledged in his testimony two months prior to this communication that he was aware that the cut-off points were not "hard and fast." This should have been a "source of serious concern" for Eastern Health in 2005 when the re-testing was underway.

On September 26, 2008, counsel for Eastern Health provided to the Commission notes of Dr. Howell dated June 10, 2008 from a meeting he had attended with Ms. Pilgrim and Mr. Wayne Miller in which the question was explored, "will we retest weak positives?"¹⁶ The actions noted included convening a group to make the decision. The names mentioned for the group included Mr. Thompson, Dr. Laing, Dr. David Saltman, Mr. Darryl Pullman, Ms. Pilgrim and Dr. Howell.

During Ms. Pilgrim's testimony on October 2, 2008, she indicated that the day before, Eastern Health had decided to carry out a review of the "weak positive." It had yet to be determined, however, who would be considered the "weak positives" for the purpose of this review.

In its final submissions to the Commission, Eastern Health stated that Daphne Coffin's testimony prompted a reconsideration by Eastern Health of whether there are other "weak positive" cases that need to be

¹⁶ Exhibit P-3319.

reviewed. A decision had been made to proceed with such a review in collaboration with NLCHI. This was anticipated to take three to six months to complete.¹⁷ The Commission inquired of Eastern Health as to who exactly would be reviewed. On February 24, 2009, Eastern Health's counsel advised as follows:

In each case where the original result was positive, where there has not been a retest, and where the patient was not given hormonal therapy, the chart review will include identification of the reasons why hormonal therapy was not used. The objective will be to find all cases that are similar to Mrs. Coffin's - i.e. where the decision to not use hormonal therapy could have been influenced by the strength of the ER/PR test score. In those cases an expert panel would review the case and determine the next steps. So, it would not really be a review for 'weak positives'. It would be a review for positive cases where a retest result has the potential to change a decision not to use hormonal therapy.

There can be no doubt that such a review has to be completed. It is commendable that Eastern Health is not only undertaking this but has expanded its scope.

Gathering the Blocks for Re-testing

In an era when computers can track interests by automatically recording websites visited, and then generate advertisements for products consistent with those interests, one might be forgiven for thinking that the identification of the ER /PR tests performed over the years would be a simple task. That was unfortunately not the case.

The difficulties were many. Chief among these was the fact that Meditech,¹⁸ or the pathology module of Meditech, was not available during all of the relevant period of 1997 to 2005 for all of the regional health authorities or, more accurately, their predecessors. Consequently, much of the searching required staff to comb through paper copies of

¹⁷ Submission of Eastern Health pp. 201-202, para. 428-429.

¹⁸ A software system (Health Information System) designed to assist health care organizations to integrate care delivery through management of data; it consists of many different components, some of which were used by Healthcare/ Eastern Health and the other three regional health authorities in Newfoundland and Labrador. (*www.meditech.com*)

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records. In Clarenville, for example, where there was a prior electronic data collection system, data was lost in the transfer to Meditech.

Clarenville

The situation, however, in Clarenville was somewhat different. Essentially, when Dr. Khalifa stopped reporting all of the ER/PR cases, the pathologists in Clarenville decided to send their cases to Mount Sinai for both IHC staining and reporting. That decision meant that very few cases from the Clarenville hospital would have met the criteria of having been stained at the General Hospital.

The Meditech systems, even those in the St. John's hospitals, all of which had throughout the period 1995 to 2005 been part of Healthcare, did not communicate with each other in 2005. Outside St. John's, many of the electronic searches performed were essentially word searches using the document content. Those doing the work would start with terms such as "breast," which would capture many more cases than those for which an ER/PR test was ordered. The documents produced by such a wide term would then have to be examined to find those where ER/PR tests had been performed, and then narrowed again to those within that group that met the criteria established by Dr. Cook.

St. John's

In St John's, ER/PR testing was done at the General Hospital, in the sense that all the ER and PR slides for the province were produced in that laboratory, though the pathologists interpreting the slides might be located at the General Hospital, St. Clare's, or before its closure, the Grace. The plan of action to complete the work of Dr. Carter has already been discussed. When Dr. Carter's work stopped, Eastern Health had to organize to ship cases to Mount Sinai. It was understood about half of the re-tests would originate in St. John's.¹⁹ The cases from other regional health authorities would first be sent to St. John's, and then would be shipped on to Mount Sinai.

¹⁹ An October 2008 revision of the Newfoundland and Labrador Centre for Health Information (NLCHI) database shows that about 49% of the re-tests originated in the St. John's region.

In St. John's, for the purpose of Dr. Carter's work, Mr. Gulliver, using the Meditech system, had identified all electronic orders (requisitions) for ER/PR tests for the period from 1997 to 2004. All pathology reports resulting from those orders, just under 3000,²⁰ had been printed and sent to Dr. Carter. When the decision was made to do the retrospective testing at Mount Sinai, as a first step Mr. Gulliver retrieved the copies of the reports from Dr. Carter's office. In the meantime, Mr. Dyer was doing searches of his own, as a check on the information obtained by Mr. Gulliver.

Mr. Gulliver and Mr. Dyer first identified the relevant pathology reports in St. John's. Pathology reports for patients outside St. John's would be with the other regional health authorities or in Carbonear and Clarenville. However, for the period prior to March 1, 1998, when Dr. Khalifa was doing all the ER/PR reporting, pathology reports were available in St. John's for the entire province.

Mr. Dyer and Mr. Gulliver then eliminated those cases that did not relate to breast carcinoma. Mr. Dyer recalled that it was later that Dr Cook added the criteria of "only primary breast carcinoma." Mr. Gulliver and Mr. Dyer looked for both ER negatives and PR negatives. The definition of negative used for this purpose was a "clinical" definition using a 10% or less, or 30% or less cut-off, depending on the time frame. Mr. Dyer's recollection was that they strictly applied the cut-off criteria. Mr. Gulliver stated that the approach was not strict, that they included cases that were "close" to the cut-off point. NLCHI has reported that Eastern Health's data included 18 cases with original ER positive results. Any discretion exercised would have been limited to those 18 patients whom NLCHI and the Task Force on Adverse Health Events (Task Force) identified as having been re-tested at the request of physicians. If the report merely said negative, as some did, it was placed with those for re-testing. If it said positive, without reference to percentage of positivity, it was put aside for Dr. Cook to examine and make a determination regarding re-testing. No case where the original

²⁰ This number included cases originating outside St. John's hospitals.

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ER report stated simply “P” or “pos” or “positive” was in fact re-tested at Mount Sinai in 2005 or 2006.

The process was made more difficult because of the number of years when the hospitals in St. John’s had separate Meditech systems. For those years where the databases within St. John’s were separate, the General Hospital would not have the results; it would just have the record of the test having been done, as with the outside St. John’s cases. They would then have to get access to the reports produced in St. Clare’s or the Grace for the relevant period. One other complication was that in 1997 and 1998 the test was not recorded as an ER/PR test, but as “peroxidase other.” So for that period they had to print out every record with peroxidase and determine what stain had been done. That basic work having been done, Mr. Gulliver and Mr. Dyer started the process of preparing spreadsheets. Dr. Carter had begun to develop a spreadsheet to record the data from her work. It was decided to continue to use that form. The process of locating the slides and blocks was then begun. They would be given, along with the pathology reports, to Dr. Cook, who was responsible for having the blocks reviewed before they were sent to Mount Sinai. Later, a list of deceased was developed so that those cases could be set aside. During the summer of 2005, Ms. Predham was asked to determine who among the patients had already received treatment with tamoxifen so that priority might be given to those who had not had that treatment. That idea was abandoned as impractical.

The Carbonear Issue: Elizabeth White

Ms. Elizabeth (Betty) White is a resident of Heart’s Content, Trinity Bay, Newfoundland. She was diagnosed with breast cancer in October 1999 and underwent surgery in Carbonear. At the time of her diagnosis and surgery, she was informed that she was ER negative and therefore hormonal treatment was not an option for her. In an addendum to her pathology report, Dr. Baker notes: “Estrogen Receptors – positive (20-30 percent of cells); Progesterone Receptors – positive (10 percent of cells).”²¹ Ms. White understood that these numbers were considered negative and the side effects of hormonal therapy would

²¹ Exhibit C-0026, p. 2.

outweigh any benefit to her. On another copy of this report, the word “positive” was crossed off and the word “negative” was handwritten on the document in place of the word “positive.”²² Dr. Baker did not make these changes.

Ms. White was referred to the Cancer Centre. Her chart notations reveal confusion as to her hormone receptor status. The referral note to the Cancer Centre from her surgeon in Carbonear states that her estrogen and progesterone receptors are positive and that she has started tamoxifen.²³ The First Assessment Summary completed by Dr. Alidina, a medical oncologist, on December 3, 1999, also refers to her as being hormone receptor positive and on tamoxifen.²⁴ Ms. White had never taken tamoxifen. She was seen by a radiation oncologist on the same date and his Progress Note states that her ER and PR were essentially negative.²⁵ On January 19, 2000, Dr. Alidina again refers in a Progress Note to Ms. White as being receptor positive. On January 20, 2000, Dr. Alidina’s Progress Note refers to her being receptor negative and therefore not needing hormone therapy.²⁶

Ms. White was advised that she would require chemotherapy. She underwent a course of chemotherapy in Carbonear during which she experienced complications that required her to be hospitalized. Following completion of chemotherapy, she was followed up at the Cancer Centre.

Ms. White first heard that there was re-testing of hormone receptor tests in October 2005, when the issue became a matter of public discussion. She recalls having a discussion with another cancer patient whose last name began with “C.” That patient had been contacted and was advised of the re-testing. At first Ms. White thought perhaps they were calling people alphabetically, and that was why she had yet to be

²² Exhibit C-0027, p. 3.

²³ Exhibit C-0029.

²⁴ Exhibit C-0030.

²⁵ Exhibit C-0031.

²⁶ Exhibits C-0034 and C-0035.

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contacted. However, as time went on and she still received no contact, she assumed it was because she was not affected.

In 2007, when the ER/PR issue was once again the subject of public discussion, Ms. White phoned the Cancer Centre to inquire whether this involved her. On July 16, 2007, she made three phone calls to the Cancer Centre.²⁷ She was referred to Ms. Nancy Parsons. She advised Ms. Parsons that she had not been contacted. Ms. Parsons' Message Log Sheet confirms the phone call from Ms. White on that date. Ms. Parsons said she would check into it for Ms. White. Ms. Parsons emailed Dr. Denic and Ms. Predham and asked to have Ms. White added to the list for re-testing.

Having heard nothing further, Ms. White on September 21, 2007, again placed three phone calls to Eastern Health.²⁸ This time she was informed that she had not been re-tested, that her specimens were in Carbonear and that arrangements would be made to have them re-tested. Ms. Parsons' Message Log Book for that date records that Ms. White called "checking on results - not back yet."

Ms. White was not provided any explanation as to why she had not been identified for re-testing in the first place. Dr. Baker's evidence sheds some light on this.

In Carbonear General Hospital, the laboratory did not store data electronically until 2004. Consequently the request in mid-June 2005 and much of the work for the larger retrospective involved examining stacks of paper. Dr. Gary Baker, the pathologist at the Carbonear hospital, described the effort to gather the results for 2002. As the reports were filed by year, the technologist in the pathology section of the laboratory and Dr. Baker's secretary examined the approximately 2500 reports for that year, identifying the breast cases, narrowing those to the ones where there was a malignancy diagnosed, determining if ER/PR had been ordered and finally determining whether the result was "negative." To do this, they looked for the word "negative" on the report. They were

²⁷ Exhibit C-0041, telephone records.

²⁸ Exhibit C-0042, telephone records.

also looking for both negative ER and negative PR tests. Any combination of negative ER, negative PR; positive ER, negative PR; or negative ER, positive PR was understood to be part of the re-test of the 2002 cases. The blocks and slides required would then be pulled and sent to Mr. Dyer at the General Hospital.

Subsequently, Dr. Baker received a phone call from Dr. Cook, who advised him to expand the effort to the period from May 1997 to May 2005. While Dr. Baker recalled that conversation was in July, it was probably in early August, around the time the St. John's hospitals were receiving a memo regarding the retrospective work. It must be remembered that by that time the Carbonear hospital had become part of Eastern Health. A similar process to that outlined for the year 2002 was undertaken for the other years.

When Dr. Baker received Dr. Cook's memo of September 6, 2005, he noted a difference from what he had earlier understood. He learned that Dr. Cook was looking only for ER negative cases, at least for those cases where the DAKO Autostainer had been used. However, by that time a number of PR negative, ER positive cases had already been sent to the General Hospital. There was another complication: the instructions from Dr. Cook talked of the cut-offs of 10% and 30%. Dr. Baker's practice was to describe a result as positive when he observed 1% or more of staining. He would then place in brackets the percentage of cells staining. For example, he might say in 2003 "positive (20% of cells)" or "positive (5 % of cells)." Dr. Baker left it to the oncologists to determine treatment based on the percentage he reported. However, in 2003 in Newfoundland and Labrador, 5% would not be considered positive by the oncologists, nor by some other pathologists.

When the September 6, 2005 memo arrived from Dr. Cook with the statement of what was considered to be positive and negative, the Carbonear hospital continued to gather the cases on the basis of the understanding they had had of the earlier oral instruction.

Dr. Baker became aware in September 2007 of ten missed patients from the Carbonear area. As noted above, it was his practice to report

any degree of staining as positive and then put percentages in brackets. Only when there was 0% staining would he report the test as negative. In the summer of 2005, his staff had been instructed to identify patients on the basis of whether the pathology report said “positive” or “negative.” They had completed most of this work before the arrival of Dr. Cook’s September 6, 2005, memo, which outlined the two cut-off points. The staff were not instructed to re-do this work.²⁹ In August 2007, Dr. Baker received a request from Mr. Gulliver to identify all breast cancer pathology reports for the relevant time period, both positive and negative. Apparently this was in relation to Dr. Reza Alaghebandan’s work on the NLCHI database. Dr. Baker asked his assistant to separate the reports into positive or negative groups. Upon review of her work in September 2007, he noticed a report in the positive group that would have been considered clinically negative but because he reported anything over zero as positive it had been grouped with the positives and not re-tested. This made him think there could have been others misclassified in the same manner, so he undertook a review of all the reports. Ten such patients were identified. Ms. White was one of them. According to Dr. Baker, her sample had, however, already been sent to St. John’s in August, 2007, before he began this review.³⁰ If this is the case, the information given to Ms. White by Eastern Health in late September (that her samples were in Carbonear) was not correct.

On October 15, 2007, Mr. Gulliver emailed Ms. Pilgrim, Dr. Howell, Ms. Predham, and Mr. Dyer, attaching a list with notations for each patient whose case had been the subject of inquiries by Dr. Donald MacDonald of NLCHI. That list contained Ms. White’s name. It was noted next to her name that her sample had been sent to Mount Sinai on August 5, 2007. However, she is also noted to be “deceased.”

Ms. White made further telephone calls to Eastern Health on November 13, 2007, to inquire as to the status of her re-test.³¹ Ms. White testified that this time she was informed her specimen had been sent to Mount Sinai for re-testing. Ms. Parsons’ Message Log Sheet for that date

²⁹ Transcript of testimony, Dr. Gary Baker, September 5, 2008, pp. 157-165.

³⁰ Transcript of testimony, Dr. Gary Baker, September 5, 2008, pp. 258-260.

³¹ Exhibit C-0043, telephone records.

notes that this was Ms. White's third call and a notation is made, "any information?" Ms. White was offered no explanation as to why, four months after she contacted Eastern Health in July, her tissue sample had still not been re-tested. It would be yet another month before Ms. White received the results of her re-test.

In December 2007, while she was out of the province on vacation, Ms. White called home to check her telephone messages. There was a message on her answering machine from Dr. Jehan Siddiqui advising that her results had changed from negative to positive, and that he would like to see her as soon as she returned. Dr. Siddiqui had spoken with Ms. White's sister-in-law, who had passed the message on to Ms. White's husband. Mr. White had been waiting until after Christmas to break the news to her. Immediately upon receiving the message, Ms. White called Dr. Siddiqui. Ms. White had apparently seen Dr. Siddiqui during one of her follow-up visits to the Cancer Centre, although she did not remember him.

Dr. Siddiqui saw Ms. White on January 17, 2008. According to the Progress Note for that date, Mount Sinai had reviewed her pathology and a "new pathology" was received for Ms. White on December 4, 2007. The re-test determined her to be 90% ER positive. However, Ms. White was not a candidate for tamoxifen because of a prior medical condition. Dr. Siddiqui discussed with her the option of an aromatase inhibitor. His Progress Note indicates that there is some role for anti-hormonal therapy even after ten years post-diagnosis.³² Ms. White saw Dr. Siddiqui again on February 14, 2008, and started a course of Femara. Over eight years post-diagnosis, then, Ms. White was placed on anti-hormonal treatment for the first time.

Central Region

The Central Newfoundland Regional Health Centre in Grand Falls and the James Paton Memorial Hospital in Gander are both operated by the Central Regional Integrated Health Authority. However, between 1997 and early 2005, when the work being reviewed was done, they

³² Exhibit C-0046.

operated under different corporations. In the case of Grand Falls it was the Central West Health Care Board and for Gander it was the Central East Health Care Board. In the summer and fall of 2005, when the blocks were being gathered for re-testing, the records of the two institutions remained separate and their Meditech systems could not communicate with each other. So, in the gathering of data for the retrospective examination, Gander and Grand Falls worked independently of each other. They approached the task differently.³³

In the Grand Falls Hospital, Meditech for anatomic pathology was implemented in 2001. In addition, the laboratory kept a log book of the ER/PR tests that had been sent to the General Hospital. In June 2005 when Dr. Cook asked for the 2002 cases, Dr. Maurice Dalton, the pathologist, and the office manager, using the list of cases sent out for testing and the Meditech system, were able to identify 16 patients who fit the criteria then established by Dr. Cook, and within two weeks the blocks were sent to St. John's.³⁴ In response to the request of September 6, 2005, a similar though much larger effort was undertaken, without the benefit of Meditech, for the period prior to 2002. By the end of September 2005, Grand Falls had forwarded its cases to St. John's. Since that time, one patient who was not identified for re-testing in 2005 has self-identified, and a subsequent review of the files at Grand Falls revealed one more patient who should have been included.³⁵ Other regional health authorities were not able to respond so promptly. It seems that a key to the ability of Grand Falls to respond promptly was the list, or log, of ER/PR tests that had been kept by the laboratory manager and that set the outside limits of the search.

Western Region

At the James Paton Memorial Hospital in Gander, Dr. Barry Gallagher was the pathologist who dealt with Dr. Cook's request. Dr.

³³ Their Meditech systems remained unable to communicate with each other at the time of hearings in 2008.

³⁴ Transcript of testimony, Dr. Maurice Dalton, July 18, 2008, pp. 248-250.

³⁵ The NLCHI database October 2008 indicates that in fact there were three patients from the Central Newfoundland Regional Health Centre who were not identified until 2008.

Gallagher could not remember receiving the memo of June 14, but he did recall Dr. Cook having called him on the subject. Dr. Gallagher understood that the Ventana was producing different results from the DAKO instrument, and Dr. Cook was interested in reviewing cases to determine why this was so. However, the request was to expand shortly thereafter. An exchange of emails on July 25, 2005 would indicate that by that point Dr. Carter wanted blocks and slides from January 1997 to December 2004. Specifically she said: “ER negative, don’t care about PR. ER/PR slides, controls, and the H & E of that block, that block report. I’m looking at the logic, type, grade, internal controls, external controls, date of testing.”³⁶ While he had no clear understanding of what was involved, by this point Dr. Gallagher recognized that this was an investigation of a serious problem, that it was not just a transition problem between two machines involving a small number of cases.

By the time of the email exchange on July 25, 2005, Gander had not gathered all of the cases for 2002. Gander had had a Meditech system since 1995, so that, unlike some of the other centres, they did not have to do manual searches. However, the process was not without challenges. Variations in the way that reports were phrased and in the terminology used made the task difficult. They in fact did three searches. The first used the word “breast”; the second, “breast” and “carcinoma”; and the third, “breast,” “carcinoma,” and “hormone receptor.” The search terms were arrived at with the assistance of the IT staff at the Gander hospital. The reports for the patients identified were then reviewed against the September 6, 2005, criteria set by Dr. Cook. Two pathologists and a technologist identified the blocks and slides which would be sent to St. John’s. Gander also sent cases from April 2004 to August 9, 2005, which would have been processed using the Ventana Benchmark, but only the negatives were sent. St. John’s did not look for the positives, though the memo of September 6 had asked for them. As it turned out, no ER positives that had been stained using the Ventana Benchmark were sent to Mount Sinai for re-testing. The idea of validating the Ventana

³⁶ The expanded search begun by Dr. Gallagher in late July 2005 was for the purpose of Dr. Carter’s work, whereas the expanded search of Dr. Baker, begun in August 2005, was for the retrospective testing to be done at Mount Sinai.

Benchmark at the General Hospital by test results from Mount Sinai must have been abandoned.

When it was discovered that a patient had been missed in Grand Falls, Gander was asked to do another search. At that point one other patient was identified because the initial search had, in fact, been restricted to female patients. Dr. Gallagher testified that only one patient was missed in the original 2005 search in Gander.

In the case of Western Memorial Hospital in Corner Brook, Dr. Cook's September 6 request arrived before the 2002 slides had been sent to St. John's. As happened in other institutions, a combination of search techniques was used. Meditech was introduced in Corner Brook in 1999. One of the features of Meditech that Corner Brook chose to implement was the ability to place a "marker" on certain data. Corner Brook had placed a marker on ER/PR tests. This enabled them to search for every case where an ER/PR test was performed. Consequently, for the period from 1999, when Meditech was introduced, to 2005, Corner Brook produced a list of patients for whom ER/PR tests were done. Prior to 1999, Corner Brook had what Dr. Paul Neil described as a "primitive" computer system, the database of which could not be searched. For the period from 1997 to 1999, other methods had to be used. Corner Brook had paper copies of all requisitions for ER/PR tests done during the period covered by the re-test. Staff went through every requisition not only for 1997 to 1999, but also to 2005 to produce a second list of those tested. As a further check, the Cancer Registry was asked to provide a list of all patients with breast cancer. From these three lists, a final list of patients with negative ER results was produced and the slides, blocks and reports were forwarded to St. John's. Some patients, however, were not identified in the process. The precise reason for the failure to identify those patients was not identified.

Labrador-Grenfell Region

The Charles S. Curtis Memorial Hospital in St. Anthony has one pathologist, Dr. Kweku Dankwa, who provides service for that hospital and others run by the Labrador-Grenfell Regional Integrated Health

Authority.³⁷ There, the Meditech system was implemented in the summer of 2003. Consequently the initial search for 2002 was a manual one. Prior to Meditech, within the laboratory, a copy of every test done for each year was stored, in one file. Within that file they were kept in alphabetical order. That method made it relatively easy to find a test result when the request came with the name of the patient, as most requests would. However, it was of no assistance in identifying cases based on test type or result. To comply with the initial request for negative test results from 2002, someone had to examine upwards of 3000 reports. The six 2002 cases that were identified for re-testing were sent to St. John's on September 8, shortly before Dr. Cook's September 6 memo actually arrived in St. Anthony. Dr. Dankwa, reported as negative those cases where there was no staining. The six cases sent would have had one or both of ER and PR tests reported as negative (zero staining). When the September 6 memo arrived, Dr. Dankwa realized that negative in 2002 was actually intended to include all those with 10% or less staining. Consequently the search effort had to be repeated for 2002.

For the period after the implementation of the Meditech system, the search in St. Anthony, like others, was conducted using terms such as "breast" and then narrowed to account for the criteria established by Dr. Cook. However, given the timing of the implementation of the Meditech system, the process to be conducted was still primarily a manual one. The work was being done by Dr. Dankwa, his secretary, and the lead technologist, all of whom had their regular duties to perform. Dr. Dankwa, knowing that nearly all their malignant cases were referred to St. John's, asked Eastern Health for a printout of all breast cancer cases that had been sent from St. Anthony for processing in St. John's. In the meantime, in St. Anthony they continued to go through their files. When the spreadsheet arrived from St. John's in late October or early November 2005 they relied on it to identify patients for the years 1997, 1998, and 1999. The gathering of all the blocks and slides was completed just before Christmas of 2005, but, concerned about sending such material in the mail at a busy time of year, Dr. Dankwa held them until January 2006. A

³⁷ There is one exception relevant to this Inquiry. During the period relevant to the Inquiry, pathology service for the hospital in Labrador City was provided by Healthcare or Eastern Health.

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spreadsheet with the results of the Mount Sinai re-tests was received in St. Anthony in March 2006, having been forwarded by Dr. Mullen to Dr. Cook by email in February 2006. By 2007, all St. Anthony's files had been reviewed manually in search of patients who might fall within the re-test criteria.

On October 5, 2005, Ms. Predham emailed Dr. Alteen. Ms. Predham said, regarding the identification of patients by other regional health authorities:

I was going through the database yesterday evening and after the conference call yesterday I noticed that some of the people whose samples we have sent away have addresses in other regions, such as Grand Falls, Labrador, Deer Lake. Would it be of any benefit to you and the other regions if I sent you their names, other demographics and sample dates? We did do the test but do you think there may be duplication of effort?³⁸

Mr. Gulliver testified that a list was compiled in St. John's, when pulling blocks for re-testing, of patients from other regional health authorities. He never thought about sending that list to the other regions to allow cross-checking to ensure no patients were missed, nor did he recall other regions asking for this list. It is clear, however, that Dr. Dankwa had requested and later received a spreadsheet listing which he used to identify patients for the years 1997 - 1999.

Ms. Bonnell, in an email two years later forwarded a document entitled "Why was Eastern Health unable to provide a complete and accurate list." The answer included in this document stated:

...However, one regret of the officials who compiled and verified the list is that is that Eastern Health did not cross reference our list of patients from outside the region with the data provided by other regions.³⁹

Mr. Gulliver responded to her email clarifying his position on this issue:

...I would rather say "in hindsight and if time had permitted the laboratory at the HSC would [have] sent copies of all test recorded in their Meditech system to the

³⁸ Exhibit P-2904.

³⁹ Exhibit P-1543.

other regions so they could cross reference with the patient results in their Meditech system...["]⁴⁰

Whether these stories reflect the general state of data management in the hospitals run by the regional health authorities I cannot say. What they do reveal is the poor state of data management within the pathology section of the laboratories. The search for specific cases was very labour-intensive. When decisions for data storage were being made, no thought appears to have been given to the retrieval of data by other than the name or number of a specific patient. This would, of course, be consistent with the traditional view of medicine as being the relationship between one patient and one physician. The reality is that that has not been the case for some time.

Aid from Mount Sinai

Mount Sinai Hospital (Mount Sinai) assisted Eastern Health and other regional health authorities on numerous occasions in 2005 and 2006. Dr. Frances O'Malley agreed to do quality assurance work for the re-testing done by Dr. Beverley Carter in the summer of 2005. By August 2, 2005, Dr. Kenneth Pritzker, Pathologist in Chief, Director of the Department of Pathology and Laboratory Medicine at Mount Sinai, had agreed that Mount Sinai would do immunohistochemical staining and interpretation of all new cases (prospective cases) from Eastern Health requiring estrogen and progesterone receptor testing. Ultimately, Mount Sinai would do the ER/PR tests for all four regional health authorities. Mount Sinai was told that they could expect 30 to 40 cases per month over a period of three months. Dr. Pritzker anticipated that they would receive the cases in batches of about five or six at a time. Mount Sinai was also doing human epidermal growth factor receptor 2 (Her2/neu) staining for Newfoundland and Labrador.

In fact, Mount Sinai did all of the prospective cases for Eastern Health until February 2007, when ER/PR testing was recommenced at the General Hospital for the laboratories in St. John's hospitals. All other regional health authorities continued to send their ER/PR tests to Mount

⁴⁰ Exhibit P-1544.

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Sinai, as did the Carbonear hospital (which by then was part of Eastern Health), except for a brief period between January and April 2008 when the General Hospital performed those tests for the Carbonear hospital. The hospital at Clarenville, which became part of Eastern Health on April 1, 2005, had been sending its ER/PR tests to Mount Sinai since 1999/2000. In the spring of 2008, because of a shortage of pathologists, Eastern Health once again asked Mount Sinai to do its ongoing ER/PR testing. Mount Sinai continues to perform those tests for Newfoundland and Labrador.

Within days of asking that the prospective cases be done by Mount Sinai, Dr. Donald Cook was making a second request of Dr. Pritzker. This time, Dr. Cook was asking that all negative ER tests for the years 1997 to 2004 be re-tested (the retrospective).⁴¹ Dr. Pritzker agreed that Mount Sinai would do the retrospective as well. The retrospective required Mount Sinai to cut blocks, produce slides, stain for ER and PR, and interpret the slides. Because the slides were to be interpreted at Mount Sinai, H & E slides⁴² would have to be produced there as well. When the slides were to be read, the pathologist would be given, for each block, an H & E slide, a slide stained for estrogen receptors, one stained for progesterone receptors, and a negative control slide.⁴³ Two positive control slides (one for ER and one for PR) were also run for each batch, but in Mount Sinai external positive control slides are read by technologists in the laboratory before the patients' slides are delivered to a pathologist.

⁴¹ The period covered would later extend to August 9, 2005.

⁴² Haematoxylin and eosin stain slides are standard diagnostic slides.

⁴³ Later in the process, Mount Sinai and Eastern Health would agree that negative controls need not be run for each block. This was done as a time-saving effort, to speed up the re-testing, after about 200 slides had been read with negative controls and therefore, Dr. Mullen had a level of confidence in the testing. However, Dr. Mullen said in his testimony that in retrospect he "probably shouldn't have, we should have stuck to our guns and gone through slowly, but it was an issue to get the results out as quickly as possible."

Dr. Brendan Mullen⁴⁴ was the pathologist chosen to interpret the slides. Though the request for the retrospective came second, it was the first work that Dr. Mullen was asked to do. He was told by Dr. Pritzker that there would be 50 to 100 slides in total.⁴⁵ Dr. Mullen knew that he would be looking at cases that had already been reported in Newfoundland and Labrador. He did not know the reason the retrospective work was being done. He did not know that the cases had been chosen because they were considered ER negative by the standards used in Newfoundland and Labrador at the time they were originally reported. He did not know what the original report had said about ER/PR test results. On September 15, 2005, Dr. Mullen was asked by Dr. Pritzker to do the prospective work as well.

Having examined the exhibits and testimony, I conclude that when the arrangements were made for the retrospective, no one at either Mount Sinai or Eastern Health had any clear understanding of how much work would be required or how much time it would really take. Within Eastern Health, at various points, the turn-around times required by Mount Sinai were said to be 3-4 weeks, 4-6 weeks, or 6-8 weeks. On August 4, 2005, Dr. Cook made a note of a conversation with Maria Mendes, Manager, Research Services, Pathology and Laboratory Medicine, Mount Sinai. According to Dr. Cook's note, Ms. Mendes said Mount Sinai could prepare slides and do staining and interpretation for 500 paraffin blocks in three to four weeks. Dr. Cook's recollection was that the first estimate of the number of cases for the retrospective that he had given to Mount Sinai was 500-550 blocks. That would have been in August or early September. He was, however, unsure about whether, at that time, he believed that number would represent the total for the province or an estimate of the number from St. John's. A note made by Dr. Robert Williams on August 8, 2005, states: "Maybe 1 ½ to 2 months to get all the reports done."⁴⁶ On August 10, 2005, Dr. Williams noted:

⁴⁴ Dr. Mullen is Director, Andrology Laboratory, Deputy Director, Pathology and Laboratory Medicine, Mount Sinai Hospital, and Associate Professor, Laboratory Medicine and Pathology, Anesthesia and Urology, University of Toronto.

⁴⁵ It is difficult to determine where those numbers came from. They are too small for even three months of prospective work and are not close to anyone's estimate of the number of cases involved in the retrospective.

⁴⁶ Exhibit P-0564.

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“four to six weeks for Mount Sinai to report these specimens.” On August 15, Dr. Williams made a note that Mount Sinai needed six to eight weeks to test.⁴⁷ The August 15 note was of a meeting with the Minister of Health and Community Services, Mr. John Ottenheimer. That estimate became the commonly accepted one within Eastern Health. Officials of Eastern Health were to note later that they also underestimated the time required to retrieve the blocks and examine them prior to shipment to Mount Sinai.

There are two laboratories at Mount Sinai capable of doing this type of work: one does routine services for hospitals; the other primarily does research work for pharmaceutical companies and others. The service laboratory participates in both the Ontario Laboratory Accreditation Program and the College of American Pathologists Program. Mount Sinai’s research laboratory meets an even higher standard established by Good Laboratory Practice set by the U.S. Food and Drug Administration (FDA). It is independently audited. While initially a small number of the retrospective cases were done in the service laboratory, for its own convenience Mount Sinai decided that the retrospective study for Eastern Health would be done in the research laboratory. The slides for the prospective cases were produced in the service laboratory. Little turns on this point except that from time to time an oncologist might want to have a particular patient’s re-test done urgently so that treatment decisions could be made. In those circumstances, the “retest” was done on a “consult basis” in the same laboratory that performed the prospective cases. As with the prospective cases, a formal report was issued for these consults and faxed to the requesting hospital. While the performance of the re-tests on a consult basis was for good reason, Ms. Predham, who along with Dr. Cook had primary responsibility for gathering the data related to the re-tests, found that these cases were more difficult to track because the results did not arrive on the retrospective spreadsheets and, therefore, were not always sent to her.

The prospective work went well. All of the regional health authorities felt they had received good service and the turn-around time

⁴⁷ Exhibit P-0570.

was satisfactory. Dr. Baker, for example, noted that the turn-around time for ER/PR testing at Mount Sinai was similar to that experienced when he sent his specimens to St. John's. The response time for the retrospective work, however, became problematic.

When the blocks arrived at Mount Sinai, they were entered into the system there, so that they could be tracked. Sometimes there would have to be communications with Eastern Health to resolve questions arising from the recording of the data. For example, on occasion there were discrepancies in numbers and dates, as surgical numbers generally contain digits meant to signify the date on which the surgery was performed. Sometimes there were problems with the blocks, which meant they had to be reprocessed before the slides could be produced. The latter issue was raised by Ms. Mendes in a telephone conversation with Dr. Cook on August 23, 2005, respecting the first shipment of blocks.

The first 115 "blocks" for the retrospective work were shipped to Mount Sinai from the General Hospital on August 18, 2005. These were identified as being from 2002, 2003, and 2004. These were not all of the blocks from those years, as Mr. Gulliver had on August 15 advised Dr. Williams that there were a total of 127 for that time frame. On the following day August 19, 2005 approximately 130 additional "blocks" were sent. These were said to be from 1999, 2000, and 2001. On August 23 or 24, 2005, 78 "cases"⁴⁸ from Carbonear and Gander were sent from Eastern Health to Mount Sinai. The first results were emailed to Dr. Cook by Dr. Mullen on September 26, 2005.⁴⁹ As of September 29, 2005, the spreadsheets from Mount Sinai to Eastern Health indicate that a total of 156 "cases" had been reported by Mount Sinai.⁵⁰ Other reports followed up to October 5, 2005. For those cases the anticipated time frame of six to eight weeks was met. As of October 3, 2005, a total of 327 cases from 1999 to 2004 had been sent to Mount Sinai by Eastern Health.

⁴⁸ It cannot be said with certainty whether a number of "cases" is meant to indicate "blocks" or "patients." For some patients more than one block was sent for re-testing.

⁴⁹ Eastern Health and Mount Sinai agreed that Mount Sinai would report the retrospective work using a spreadsheet format.

⁵⁰ A briefing note, Department of Health and Community Services, dated October 3, 2005, states that to that date 153 "samples" had been reported.

There were three DAKO Autostainers in the research laboratory at Mount Sinai, one of which was reserved for ER/PR testing. It could do 15 cases per day. A second Autostainer might also be used for that purpose. The third was reserved for other types of immunohistochemistry (IHC) testing. However, in mid-October, one of the Autostainers dedicated to ER/PR staining had to be taken out of service. It was eventually replaced by a LabVision 720, but by the time that occurred and the validation process was completed within the laboratory, it was the end of November.

By October 20, 2005, Ms. Nancy Good of Mount Sinai reported to Dr. Cook that she had logged into their database approximately 547 patients – all that they had at that point. By mid-November, Dr. Pritzker was telling Dr. Cook that they had “done 200 with 500 to go.”⁵¹ Whether that was 700 cases or blocks is not clear (Pritzker, June 23, 2008, p. 239). On November 3, 2005, in an effort to set priorities for the work, Ms. Predham, at the request of Dr. Cook and Dr. Williams, identified for Mount Sinai the patients on Mount Sinai’s list who were deceased and asked that those cases be processed later. As of December 19, 2005, Mount Sinai had received a total of 861 cases (934 blocks) for the retrospective. Only 225 cases had been reported at that date as part of the retrospective. An additional 12 cases had been pulled for consults. Eastern Health was pressuring Mount Sinai for results.

Mount Sinai accelerated their efforts during Christmas 2005. On January 20, 2006, the “final” report was sent to Dr. Cook. In fact, it was not the final report. NLCHI has determined that as of August 12, 2008, 1023 patients had been re-tested. Efforts are continuing at Eastern Health to ensure that all patients who meet the criteria for re-testing have been identified.

When the Results Were Received from Mount Sinai

By September 6, 2005, when Dr. Cook asked the other regional health authorities to send their cases, most of the St. John’s cases had

⁵¹ Transcript of testimony, Dr. Kenneth Pritzker, June 23, 2008, p. 239.

been identified and the blocks pulled. As a result, the first cases reported by Mount Sinai were primarily Eastern Health patients.

For the retrospective examination, Dr. Mullen sent Dr. Cook the results on a spreadsheet. Using the spreadsheet, Dr. Cook, for the Eastern Health patients, would dictate and sign an addendum to the chart of the patient.⁵² For patients from other regional health authorities, Dr. Cook conveyed the results to the appropriate regional health authority, and a pathologist from that organization dictated and signed the addendum. A system, which will be discussed in more detail later in this report, was established to communicate with the patients. Generally speaking, for patients whose test results were unchanged, there would be a phone call advising them of the results. For those patients whose test results had gone from clinically negative to positive, there was a process whereby the results would be examined by a panel of physicians (the Panel) and a letter written to the principal treating physician recommending what options should be presented to the patient in the circumstances.

⁵² This presented a problem where the patient had died. The efforts to resolve that problem are discussed in the portion of the report dealing with communications.

Chapter Seven

The “Investigative” Effort

The “Investigative” Effort

Efforts to Find Out What Happened

Dr. Carter’s investigation having ceased on August 2, 2005, Eastern Health turned to others to help them find out why so many tests’ results had changed.

Heather Predham’s Investigation

As a first step, however, it was decided that Ms. Predham would do a “quality review” of the immunohistochemistry section of the laboratory. On August 2, 2005, she set out to do a review. Ms Predham spoke to three technologists: Ms. Mary Butler, Mr. Les Simms, and Mr. Ken Green. At her request, they explained the production of ER and PR slides from the grossing of specimens to the staining of the slides. Ms. Predham was comfortable with the descriptions the technologists were giving of what they were doing in 2005, using the Ventana Benchmark. However, there was no real documentation of the process. For example, there was inadequate documentation of control slides having been run. The technologist referred to a manual from the company that manufactured the Ventana Benchmark as representing the standard procedure they followed and they also referred her to a text book. Ms. Predham believed documentation was fundamental for any quality review process. She was unable to examine the process using the DAKO Autostainer because that instrument was no longer available.

Ms. Predham also found that there was no comprehensive quality assurance process. She realized that the technologists saw feedback from pathologists as their key quality assurance process, but she could not see how that could possibly work, with so many pathologists reading ER/PR slides and the possibility of disagreements among them as to the quality of the slides or possible actions to be taken to improve quality. Later she learned that the pathologists were not even aware that they were viewed by technologists as part of the quality assurance process.

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The technologists also told Ms. Predham that they did not believe there was good communication between them and the pathologists. They complained that there was no one designated pathologist whom they could consult if they had a problem or through whom the pathologists could communicate with them. Ms. Predham observed that from the perspective of quality and risk management there should be someone in the division who had the role of validating concerns raised by either the technologists or pathologists.

Later that day Ms. Predham talked to the two site chiefs, Dr. Cook (St. Clare's) and Dr. Dan Fontaine (General Hospital), about what she had seen and heard. Subsequently she also spoke to Mr. Gulliver and Mr. Dyer.

Ms. Predham came to see the IHC laboratory as being divided into two camps: technologists and pathologists. Having had experience with other parts of the laboratory over the years, she saw immunohistochemistry as not having the kinds of quality controls that existed in those other sections of the laboratory. She concluded of immunohistochemistry: "this was like a little pocket where it hadn't been set up well."

Ms. Predham advised Dr. Williams that they needed to retain someone familiar with immunohistochemistry laboratory procedures to examine the laboratory. She also told him the problem was too big to use a root cause analysis method of examination.

The External Reviews

Eastern Health had meanwhile embarked on the process of arranging for two experts to come to St. John's. Dr. Diponkar Banerjee is the Provincial Program Leader, Cancer Pathology for the British Columbia Cancer Agency and Director of Laboratories at the Vancouver Cancer Centre. He is also a Clinical Professor of Pathology and Laboratory Medicine at the University of British Columbia. Ms. Trish Wegrynowski is a Senior Medical Laboratory Technologist, Immunohistochemistry at Mount Sinai Hospital, Toronto. These two individuals visited separately; Dr. Banerjee on September 15 and 16, 2005,

and Ms. Wegrynowski from September 20 to 22, 2005. Dr. Banerjee was to examine the work of pathologists, Ms. Wegrynowski that of the technologists. Each was very well qualified for the task. Each gave an “exit interview” which was followed by a written report. Those reports, which were dated October 17, 2005 (Banerjee),¹ and November 9, 2005 (Wegrynowski),² respectively, were received by Eastern Health shortly after those dates. Because Eastern Health believed these reports to be confidential, initially only four copies of each were made.

Dr. Cook knew Dr. Banerjee because they were both involved with the activities of the Canadian Association of Pathologists. Dr. Banerjee recalled that in their initial conversation about the ER/PR issue, Dr. Cook expressed concerns about the conversion rates between the old technique (using the DAKO Autostainer) and the new one using the Ventana Benchmark. Dr. Banerjee’s first thought was that perhaps the problem was improper optimization of the Ventana system causing “overcalling” of positivity. Perhaps the DAKO was fine. Dr. Banerjee’s experience with DAKO Autostainers was positive. He doubted that the DAKO instrument was the problem. However, as he talked further with Dr. Cook he realized that test results were being reported without consideration of internal controls. This concerned him. Before he came, Dr. Banerjee specified certain things he wanted to do: “I will need to review any laboratory procedure manuals and a random selection of IHC slides before and after switching to the Ventana platform, including positive and negative controls slides, not just for ER and Her2/neu, but all antibodies on your menu. If you have cases stained with both old and new methods on the same block, those would be helpful as well.”³ Dr. Banerjee explained to the Commission that he wanted to see other than ER or Her2/neu slides because he was looking for some kind of pattern of non-specific staining or false negative staining as a result of some lack of optimization and methodology. He wanted to see procedure manuals to see whether the test optimization was done in the laboratory in St. John’s or if they were merely following the manufacturer’s instructions.

¹ Exhibit P-0046.

² Exhibit P-0047.

³ Exhibit P-1969.

He warned that the latter might not necessarily work in the laboratory in St. John's. Dr. Banerjee described his task as follows:

My understanding was that I was being asked to figure out what the problem was with their immunohistochemistry service, and I was approaching it from the point of view of an experienced immunopathologist who could troubleshoot for them and advise them about how they could improve the process.⁴

When Dr. Banerjee came to St. John's, he reviewed a selection of cases that had been chosen by Dr. Cook. As Dr. Banerjee had requested, not all were ER cases. He was not shown any laboratory manuals. In his October 17, 2005 report, Dr. Banerjee noted that all ER cases that had changed from clinically negative to clinically positive had one or more of three characteristics:

- 1) Poor fixation,
- 2) Negative internal control (normal ductal epithelium, when present, was completely negative), and
- 3) Absent internal controls (no normal ductal epithelium present to evaluate).

Dr. Banerjee observed that too much reliance was being placed on external positive controls with no attention paid to internal controls.

As to the reasons for the test failures, Dr. Banerjee rejected the notion that the cause was a faulty DAKO Autostainer or that the Ventana Benchmark was too sensitive. However, in his testimony he added that it was apparent that there was a lower intensity staining using the DAKO system than with the Ventana system. This suggested to Dr. Banerjee that either there was a problem with the antigen retrieval process or the antibody concentrations being used, or the detection system concentrations were not optimal. He also noted that the fact that there were more positive results using the Ventana Benchmark supported the view that all of the problems could not be laid at the door of inadequate fixation. He concluded that a combination of factors was at work, including inadequate or poor fixation and method of optimization, which

⁴ Transcript of testimony, Dr. Diponkar Banerjee, July 30, 2008, p. 70.

led to the false negative staining. The Ventana Benchmark, because of the use of pre-diluted reagents and the antigen retrieval process being built into the machine, was able to compensate for and thereby overcome the problem of poor fixation. However, there was also more background staining on the Ventana-produced slides, which Dr. Banerjee attributed to a failure to optimize the Ventana system.

In his report, Dr. Banerjee returned to the theme he had started with and opined that:

- (1) Inadequate attention was being paid by the grossing pathologists to the thickness of tissue slices and the quality and adequacy of fixation, and there was no standardized fixation protocol that everyone adhered to.
- (2) Inadequate or no attention was being paid by the reporting pathologists to the status of internal controls, with inappropriately exclusive reliance on external positive controls. “Negative test results in the absence of positive internal controls should have triggered corrective procedures ... and should not have been released without troubleshooting, and in the event that poor fixation resulted in internal controls failure in all available blocks, this should have been noted in the reports as an uninterruptible case due to failure or absence of internal controls.”
- (3) Inappropriate choice was made of blocks with no representative normal ductal epithelium.
- (4) Better education was required for technologists, pathologists and clinicians about the pitfalls of IHC, the importance of quality control, and the interpretation of IHC results.

Dr. Banerjee suggested certain actions to ameliorate the problems, including suggestions regarding the management structure in the laboratory, which I shall return to later in this report.

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When one looks to a letter written three months earlier, on July 28, 2005, from Dr. Cook and Dr. Carter to all pathologists and pathology residents in the St. John's Hospitals of Eastern Health, the similarities in the points made respecting the work of the pathologists is striking. In providing advice to their colleagues, Drs. Carter and Cook noted the following regarding "Optimal Assessment and Reporting of Hormone Receptor Status in Infiltrating Carcinoma":

When ordering and reporting ER/PR status on infiltrating carcinoma of the breast:

- 1) Select a block that contains infiltrating carcinoma and normal and/or benign breast epithelium.
- 2) When reporting, always check internal and external controls.
- 3) The external positive control should show some variability of staining throughout the tissue section.
- 4) The external negative control, if made available, should show no staining.
- 5) The internal negative control (eg. stroma, vascular endothelium) should show no staining.
- 6) Internal breast epithelium should show some positivity (but not diffuse).
- 7) If the external positive control is negative, the test is invalid.
- 8) If the external negative control is positive, the test is invalid.
- 9) If the internal control shows aberrant staining, the test may be invalid; please refer to Dr. Bev Carter.⁵

Ms. Wegrynowski's report was directed to the role of the technologists. Of particular note in her report were the following:

1. Very informal protocols and documentation exist in either laboratory [St Clare's and the Health Sciences]. Procedure Manuals detailing the Standard Operating Procedures [for fixation and grossing] do not exist at either site.
2. Procedure manuals outlining the Standard Operating Procedures for the Tissue Processors were not found. Neither signed documentation for the daily maintenance of the processors nor temperature monitoring of the paraffin wax was found.
3. There is no Medical Section Head for the IHC Laboratory. There are no clear lines of communication. "... the technologists are overwhelmed as they do not completely understand the theory of IHC and this testing requires high technical proficiency to troubleshoot the methodology."
4. Documentation was deficient. Ms. Wegrynowski specified key areas where this was evident.
5. No negative controls were being used at the time of her visit.

⁵ Exhibit P-0076.

6. There was no standard reporting format.
7. Neither external quality assurance nor inter-laboratory comparison was being performed at that point.
8. No documentation existed regarding training of staff to perform their duties; competency assessment for all staff was not performed in the pathology division.⁶

In his letter of May 24, 2005 to Dr. Williams, Dr. Cook had included the following suggestions for immunoperoxidase testing:

- 1) The immediate establishment of an external proficiency testing and monitoring program for immunoperoxidase testing.
- 2) The establishment of a separate immunoperoxidase service with at least three technologists solely dedicated to immunoperoxidase testing with separate testing facilities.
- 3) The training of immunoperoxidase technologists in a major immuno – referral lab that has a well established quality control and trouble shooting program
- 4) Appropriate CME funding for these immunotechnologists.⁷

Inquiries of Dr. Ejeckam

Not until March 7, 2006, did anyone ask Dr. Ejeckam what he had meant by “erratic” in his April 4, 2003, memorandum. He told Dr. Cook and Mr. Gulliver that for the eight IHC stains involved, on some days a stain would work and on others it would not. When Dr. Cook then asked whether Dr. Ejeckam should in 2003 have recommended a review of prior ER/PR cases, he replied that it had not been his place to initiate or recommend such a review. Dr. Ejeckam testified that in 2003 he was not aware of any ER/PR case that had been re-tested and produced clinically different results. In 2003, Dr. Ejeckam believed that pathologists would not report results unless they considered them reliable. He explained that he had temporarily halted ER/PR testing in 2003 because of the need to repeat tests to obtain reliable results. Dr. Ejeckam felt he never did possess any real authority in relation to the IHC service. He acted as he did in 2003 because no one else did. He noted that the first time there was

⁶ Exhibit P-0047.

⁷ Exhibit P-0067 p. 3.

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any reference to him having responsibility for the IHC service was late in 2005.⁸

The External Reviewers Return

In early March 2006, Dr. Williams asked Ms. Wegrynowski to return to St. John's to review how far Eastern Health had progressed in implementing the 42 recommendations in her November 9, 2005, report. She agreed and requested copies of written protocols and procedures to review before her arrival. All she received was a spreadsheet created months before that listed in bullet format recommendations from a variety of sources. On visiting the General Hospital on March 30, 2006, she learned that no standard operating procedures had yet been written. During this one-and-a-half day visit, unlike the earlier one, she was restricted. She only went to the IHC laboratory. She was not to interview pathologists or visit the St. Clare's site. She recalled that "they had started to implement some of the recommendations, but they were a long, long, long way to completing them."⁹ She was surprised that after six months there was still not much documentation in place. She explained that had she been free to do so she would have "gone right back down to the basics to make sure that those corner stones were in place before we moved on with immunohistochemistry."¹⁰ Those "corner stones" were standard operating procedures for fixation and tissue processing. Ms. Wegrynowski participated in an exit interview.

Ms. Wegrynowski subsequently provided a report dated May 2, 2006.¹¹ In it she listed 32 recommendations, a number of which she had made earlier. She summarized her view of the situation at the end of her second visit as follows:

⁸ Dr. Ejeckam also wondered why, if he was actually in charge of IHC, Dr. Cook refused to give him a copy of Dr. Diponkar Banerjee's September 2005 report (discussed elsewhere) on how to improve the IHC service. This refusal came after Dr. Cook had read that report to all the St. John's pathologists. Dr. Cook told Dr. Ejeckam that if he wanted to read it himself he would have to do so in Dr. Cook's office.

⁹ Transcript of testimony, Ms. Trish Wegrynowski, June 24, 2008, p. 338

¹⁰ Transcript of testimony, Ms. Trish Wegrynowski, June 24, 2008, p. 354

¹¹ Exhibit P-0048.

They had begun to look at the process. The procedures manuals were nowhere near where I thought they might have been. Some of the basics, I felt were still missing, refrigerators, pipettes. They had started on the external quality assurance programs, but in my humble opinion, if you don’t start at the bottom, you can only take the top up so far.¹²

Dr. Diponkar Banerjee, at the request of Dr. Williams, returned to St. John’s on April 24, 2006. His task was to determine whether the quality of IHC had improved since his September 2005 visit, and whether the recommendations in his October 17, 2005, report had been implemented. He found there had been “a significant improvement” in the quality of staining, as the earlier problem of background staining had been dealt with. He examined recently prepared slides related to both hormone receptors and other types of IHC stains. He testified, “so I was quite happy with this improvement I saw.”¹³ He added, “I felt that they were doing as well as most hospitals that I’ve seen.”¹⁴ However, he acknowledged that fixation problems had still been apparent. Dr. Banerjee participated in an exit interview. He produced a report dated May 21, 2006, that listed ten recommendations.¹⁵ He noted that an earlier recommendation that the organizational structure of the laboratory be changed to provide joint technical and medical accountability, planning, and communications had not been implemented.

Dr. Banerjee acknowledged that in the fall of 2005 and spring of 2006 he had not been made aware of the reviews conducted by Ms. Wegrynowski. He learned that the chief IHC technologist from Mount Sinai was involved only after the Commission of Inquiry was announced. Having in 2008 reviewed Ms. Wegrynowski’s two reports, Dr. Banerjee said that while they would not likely have made a difference to his conclusions, “I think I would certainly have preferred to have seen that report because perhaps some of my recommendations would have been in greater detail, particularly on the technical side.”¹⁶

¹² Transcript of testimony, Ms. Trish Wegrynowski, June 25, 2008, p. 27

¹³ Transcript of testimony, Dr. Diponkar Banerjee, July 30, 2008, p. 200

¹⁴ Transcript of testimony, Dr. Diponkar Banerjee, July 30, 2008, p. 204

¹⁵ Exhibit P-0049

¹⁶ Transcript of testimony, Dr. Diponkar Banerjee, July 30, 2008, p. 265

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The 2006 reports of Ms. Wegrynowski and Dr. Banerjee were handled by Eastern Health in a manner similar to their 2005 reports. Numbered copies were made, and distribution was again limited to a very small group within Eastern Health.

Dr. Cook and Dr. Williams knew about the problems that had been observed by Dr. Carter in her review of over 90 patients in the summer of 2005. None of what was said by Dr. Banerjee or Ms. Wegrynowski could have come as a surprise to those three, two of whom were members of the Core Group. There was also another source of information. When the decision was made to have the retrospective work done at Mount Sinai, Dr. Dan Fontaine, the site chief at the General Hospital, was asked to identify alternative blocks to be used in the event that the original block and slides were not available. So then, Dr. Fontaine did not examine the original ER/PR slide.¹⁷ He looked at everything else for the purpose of choosing the most appropriate alternative, if it was necessary to use one. His observations, therefore, were not in relation to the slides used to report ER/PR test results, a percentage of which had resulted in erroneous test results. Rather, he examined all other blocks produced at the same time as the slides read for the ER/PR testing. After he had completed his task, Dr. Fontaine felt compelled to write a letter to Mr. Gulliver about his observations and suggestions. That letter was copied to Dr. Williams and Dr. Cook. Dr. Fontaine made the following points in his letter of September 21, 2005:

1. the problem extends “far beyond” the estrogen and progesterone receptor status;
2. there is a need for a dedicated immunohistochemistry laboratory with highly trained technologists, dedicated to immunohistochemistry service, “who are at the leading edge of the field who are trained to interpret and troubleshoot any possible inconsistencies with staining patterns”;
3. there should be participation in an external quality assurance and monitoring program;
4. there is no standardized approach to grossing specimens, which is best remedied by the introduction of pathology assistants.¹⁸

¹⁷ Dr. Cook understood that Dr. Fontaine was reviewing the original slides for the General Hospital. Dr. Williams was of the same view, as was Mr. Gulliver.

¹⁸ Exhibit P-0595.

With the exception of the first observation, Dr. Fontaine was repeating points that had been made by Dr. Carter and Dr. Banerjee, and would be made shortly thereafter by Ms. Wegrynowski.

Dr. Mullen's Review

In April 2008, at the request of the Commission, Dr. Brendan Mullen, who had read the slides produced for the retrospective study, read 539 pairs of the original ER and PR slides stained at the General Hospital during the relevant period. The 539 were chosen using a database produced by the Newfoundland and Labrador Centre for Health Information. Basically, they are those cases where the results, as determined by Mount Sinai on the re-test (retrospective study), were ER positive in one or more percent of the tumour cells' nuclei. In other words, they were all determined to be ER positive according to the standards used at Mount Sinai, not those used in Newfoundland and Labrador. Dr. Mullen summarized his findings in a letter, a portion of which is reproduced below:

To summarize my observations, the overwhelming majority of cases had one or more the following problems:

1. Poor fixation or processing resulting in incomplete tissue sections, loss of the internal structure of the nucleus and staining restricted to the periphery of the slide. In our previous conversation, the incomplete tissue section issue was referred to as "exploding" sections. In some of the material I reviewed, the "exploding" sections resulted in loss of the invasive tumor on the ER/PR slides although it was present in the initial H&E section. The second issue, loss of the internal structure of the nucleus, we discussed as "hollow" nuclei. Because of poor fixation, the nuclear substance is lost and markedly decreases the chance of staining for ER/PR. The third issue, staining restricted to the periphery of the slide, refers to staining at the periphery of the section with absence of staining centrally. It is difficult to interpret the results of these cases as the peripheral staining results may not reflect the results of the entire tumour.
2. Absence of the internal controls. Many of the cases had no normal duct epithelium to use as an internal control on the initial H&E section. Additionally, in many cases where the original H&E section had normal duct epithelium, it was not present on the ER/PR slides as a result of the "exploding" section issue.
3. Negative internal controls. In many cases, the internal control either did not stain or stained very weakly. Also, with the exception of a small minority of cases, the ER internal control was significantly weaker than the PR internal control.

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4. Stain deposit obscuring morphology. In many cases excess stain was present either on the surface or beneath the section. Both artifacts preclude assessment of the ER/PR staining in areas affected.
5. External controls. The external controls were inconsistent both between slides and within slides. In some cases, the positive cells were barely stained. In occasional cases from 2005, the controls stained both the nucleus and the cytoplasm reflecting inadequate or incorrect validation.
6. Discrepancy between internal and external controls. In only one or two of the 539 cases I reviewed was the staining in the internal control as strong as the corresponding external control.

There were very few cases in which there was a significant difference in my observation compared to that recorded on the original report. Some of my observations were higher than those recorded and some lower.¹⁹

There are obvious consistencies among the observations of Dr. Carter in the summer of 2005, of Dr. Banerjee in September of that year, of Dr. Mullen in his January 20, 2006 comment on substantially completing the retrospective and of Dr. Mullen in April 2008 after reviewing approximately one half of the original slides. While Dr. Carter's and Dr. Banerjee's reviews concentrated on the slides produced in 2002, Dr. Mullen's observations were based on an examination of all the ER and PR slides prepared at Mount Sinai using blocks produced in Newfoundland and Labrador from 1997 to 2005, in the one case, and many of the original ER and PR slides produced at the General Hospital over the full period of 1997 to 2005, in the other.

Publicly, officials of Eastern Health have taken the position that they do not know what caused the many "conversions" because they are unable to relate the particular deficiencies that were identified to any individual case. In testimony before the Commission, one witness from Eastern Health talked of a plan to try to determine whether fixation was the cause by trying to do correlations between the cases where there had been conversions and those where fixation had been identified as problematic. That project had not then been undertaken. Another witness from Eastern Health opined that the problem could not have been fixation because Mount Sinai was able to do the re-tests in spite of the fixation problems. I found it difficult to reconcile these simplistic views of

¹⁹ Exhibit P-1840.

the problem with the often stated position of Eastern Health that ER/PR testing is complex. If the test is complex, why would one assume that the problem must be attributed to only one aspect of the testing? On the other hand, when Eastern Health made the decision in 2007 to recommence ER/PR testing, it did so with confidence on the basis of the implementation of the recommendations of Dr. Banerjee and Ms. Wegrynowski. I can only conclude that in 2007 Eastern Health was satisfied that the combination of deficiencies identified by the work of Dr. Carter, Dr. Banerjee, and Ms. Wegrynowski, and subsequently confirmed by Dr. Mullen, had caused the "conversions" and that those deficiencies had been eliminated, thereby making it safe to reinstate ER/PR testing.

Disposal of the DAKO Autostainer and its Electronic Records

Joseph White is a self-employed service technician for hospital laboratory equipment. Over the last 20 years, he has serviced equipment in hospitals throughout the province. He was familiar with the St. John's hospitals and their laboratory technical management personnel, including Mr. Gulliver and Mr. Dyer. He had observed that the laboratory medicine program in St. John's did not appear to have adequate resources to maintain its equipment satisfactorily.

In late 2004 or early 2005, Mr. Gulliver authorized Mr. White to take possession of the DAKO Autostainer, including its computer. No money changed hands, nor was any paperwork completed to document this transaction. Mr. White, after cleaning the instrument and carrying out some preventative maintenance, sold it, together with its computer, to a pathology brokerage company in the United States, which in turn sold it to the University of Virginia. The instrument and its original computer are still in operation in a research laboratory at the University of Virginia.

Early in the investigation of the ER/PR matter in 2005, Dr. Williams inquired of Mr. Gulliver whether the specimens could be repeated on the "old" DAKO system to confirm that it was indeed an equipment problem and not a laboratory error.²⁰ Mr. Gulliver advised

²⁰ Exhibit P-0075, Briefing Note, July 20, 2005.

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that it was unlikely they would be able to obtain such a system at that time. Of course, the DAKO system was still widely used throughout Canada, including at Mount Sinai Hospital, where the re-tests were ultimately carried out. Surprisingly, even though the instrument had been given to Mr. White only a few months prior to Dr. Williams' inquiry, and notwithstanding that Mr. White remained in frequent contact with Mr. Gulliver and others in the laboratory, no one asked Mr. White where the instrument was.

It was not until 2008, when the Commission asked questions of Eastern Health as to the fate of the DAKO instrument and its records, that inquiries were made of Mr. White. By that time, Mr. White could not recall if he had received the computer or just the instrument itself. Mr. Gulliver said that "there were no records kept with the DAKO machine's hard drive."²¹ Mr. White helped the Commission to track down the instrument and its computer. After a couple of phone calls, Commission Counsel was in contact with Dr. James Mandell, principal laboratory investigator, Department of Pathology, University of Virginia, who confirmed that the University of Virginia was in possession of the instrument with its original computer, having obtained it in July 2005. Very quickly it was further determined that the computer software had not been erased and contained records from Eastern Health. Dr. Mandell was very cooperative and helpful to the Commission in its efforts to recover the original electronic records, and he personally undertook the work that resulted in the electronic data being retrieved and forwarded to the Commission. There is no reason to believe that Eastern Health would have been treated any differently by Dr. Mandell, had it made efforts to find the DAKO Autostainer.

The electronic data that was recovered has since been provided by the Commission to NLCHI which, in turn, has engaged the services of Ms. Trish Wegrynowski of Mount Sinai Hospital to analyze the data. While this analysis is ongoing at the time of writing this report; it has been determined that information contained in the electronic data might have been of some assistance to Eastern Health at the time it was faced

²¹ Exhibit P-3110, p. 2; email correspondence from Daniel Simmons, counsel to Eastern Health, to Commission Counsel, September 18, 2008, quoting Mr. Terry Gulliver.

with the ER/PR review. It is not yet determined if the electronic records still exist for all of the ER/PR tests conducted in the relevant time period. The data that does exist includes surgical numbers and run identifications. Surgical numbers can be used to identify patients. This information could have been useful as a cross-reference in determining if all patients had been identified. Further, the run identification data may have been used to identify particular runs that had tests with changed results or to identify other patients whose tests were performed in the same run as a patient who had a changed test result. The data also contains information as to the particular protocols in effect in the laboratory at different times. Whether any other use could be made of this data should be further investigated. For example, I would expect that the surgical numbers contained in the electronic data would now be used as a cross-reference to help ensure that all of those patients who required re-testing have been identified. Furthermore, an analysis should be undertaken to determine whether the data can provide any useful information on the cause of the changed results, such as whether there is any correlation between the changed results and particular runs.

It is obvious that the electronic records should never have left the possession of Eastern Health. Furthermore, efforts should have been made in 2005 to recover the DAKO Autostainer and the original data contained in its computer hard drive.

Chapter Eight

Patient Safety

Patient Safety

Patient Safety Movement

Quality is costly

The patient safety movement is about two decades old. Its origins can be traced to a number of studies and to a report by the United States National Academy of Science, *To Err is Human: Building a Safer Health Care System*, which examined adverse events. A Canadian contribution to this movement is found in *The Canadian Adverse Events Study*.¹ These studies identified a rate of unintended injury or consequences in health care delivery that has shocked the public and the health care community. In their article “Disclosing medical errors to patients: A status report in 2007,”² Wendy Levinson and Thomas Gallagher summarized the results of a number of studies as follows:

Studies from multiple countries, including a Canadian study by Baker and colleagues, have estimated that adverse events affect up to 7.5% of patients admitted to acute care hospitals. Baker and colleagues estimated that 37% of those adverse events could be considered preventable.

As a consequence of the development of the patient safety movement, attention has been focused on certain essentials of health care which are relevant to this Commission’s work: the need for policies regarding disclosure of adverse events, the need to develop systems that enable a wider learning experience from adverse events, the need for policies to support patient safety, and the need to implement systems to improve safety.

In May 2008, the Canadian Patient Safety Institute (CPSI) published the *Canadian Disclosure Guidelines*. I shall return to the guidelines when discussing the communications with patients who were re-tested and what should be done in the future. As a background to the issue of disclosure, the *Canadian Disclosure Guidelines* also discuss the

¹ G. Ross Baker, P. Norton, et al., *The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada*, CMAJ 2004; 170 (11): 1678.

² CMAJ 2007; 177 (3): 265-67.

importance of the development of a patient safety culture in health organizations. The notion of a patient safety culture was not new in May 2008, nor was the obligation to disclose adverse events to patients. The guidelines were an attempt by a number of different groups to come to a consensus on the subject. The subject of patient safety was addressed by officials of Eastern Health during their testimony at the Inquiry. The CEO in 2005, Mr. George Tilley, in particular, was a strong advocate of the idea of a “blameless culture,”³ perhaps because he had been a member of the board of the Canadian Patient Safety Institute from 2003 to 2006.

A culture of patient safety would include an environment in which adverse events are openly identified and reported. Reporting is defined as “the communication of information about an adverse event or close call by healthcare providers, through appropriate channels inside or outside of healthcare organizations, for the purpose of reducing the risk of recurrence of adverse events in the future.” The *Canadian Disclosure Guidelines* also express the view that:

[m]any adverse events in healthcare are now recognized as system failures, where safeguards to protect patient safety were not in place, or a series of safeguards that were in place failed in sequence, which resulted in harm to the patient. Adverse events often occur after recurrent patterns of failures, regardless of the dedication or experience of the healthcare providers involved. Systems theory emphasizes that focusing on the system rather than on the individual will prevent more adverse events.

A “just culture” is a key element of a broader patient safety culture that seeks to reconcile professional accountability and the need to create a safe environment in which to report adverse events. Healthcare providers in a just culture are fully aware of the expectations of the organization and are held professionally accountable for the quality of their work in a fair way. Adverse events are viewed in the context of identifying system contributors in order to improve safety. The adverse event is analyzed for such system contributors, and the lessons learned are used to strengthen the system and, if appropriate, to support and educate the healthcare providers to help prevent similar events.⁴

³It is now more common to see references to a “just culture” than to a “blameless culture.”

⁴ Exhibit P-0161, pp. 12-30.

The definitions of “adverse event” in publications are not entirely consistent. The CPSI (2008) definition is:

An event which results in unintended harm to the patient, and is related to the care and/or services provided to the patient rather than to the patient’s underlying medical condition.⁵

As was pointed out in a memorandum submitted to this Commission by the Healthcare Insurance Reciprocal of Canada (HIROC), the weakness of this definition is that it does not clearly articulate that included in the concept of adverse event there should be recognition of those cases where the result is a risk of a non-trivial adverse outcome or consequence in the future. For the purpose of this report I adopt the definition⁶ contained in the HIROC paper prepared by Professor Elaine Gibson:

An unexpected event in healthcare delivery that results in harm to the patient and that is related to the care and/or services provided to the patient, rather than to the patient’s underlying medical condition. This includes an incident in the course of health care treatment which results in a recognized risk of a non-trivial adverse outcome or consequence at some future time.⁷

I recognize that it is difficult to determine potential for harm. Any such determination requires the exercise of judgment that may be biased. However, in the context of this Inquiry, it is important to include in the category of those considered as having suffered an adverse event those patients who were not considered for anti-hormonal therapy because they were, in error, reported as ER negative and who, to this point, have not had any recurrence of their breast cancer.

⁵ Exhibit P-0161, p. 30.

⁶ Of course, where the term “adverse event” is used in a policy or study, the definition contained in that policy or study should be examined to ascertain the author’s meaning.

⁷ Gibson, Elaine *Memorandum on Duty of Disclosure in Canadian Law: Submission for Part II of the Newfoundland and Labrador Hormone Receptor Commission of Inquiry* (May 14, 2008), p.3.

Quality Initiatives

The Policies

From April 1999 onward, Healthcare had a formal process for the development of quality planning. The document, *Implementing a Quality Plan*, explained how Healthcare defined quality,⁸ the model being adopted, and the reporting format to be followed. This was not just a broad statement of ideals. There were details for the development of a quality plan, details concerning its stages and how to go about following each stage. There were also instructions on team building, including instructions on the four stages of team building⁹ and how to obtain consumer feedback, including how to conduct consumer surveys and collect data from focus groups.

The role of the Quality Department¹⁰ was described as follows:

The Department of Quality Initiatives exists to provide leadership and support to all Programs and Departments of the Corporation in their efforts to continually improve the quality of care and service delivered. The main areas of focus are Risk Management, Utilization Management, Consumer Feedback, Performance Measurement, and Outcome Evaluation. As well, the Department provides an assortment of educational sessions to support these activities.¹¹

Ms. Pamela Elliott and Ms. Heather Predham both testified that the necessary expertise for the development of quality initiatives lay within a program or department, not within the Quality Department. Therefore, it was logical that the Quality Department play a support role. The primary responsibility for the implementation of quality initiatives and “accountability for quality for care” lay with the programs and departments within Healthcare:

⁸ “Quality means doing the right things right and making continuous improvement.”

⁹ Healthcare adopted Bruce Tuckman’s model of group development which included four phases: forming, storming, norming and performing.

¹⁰ The department or program responsible for quality has had different names over the years. For convenience, whatever its name, I shall refer to it as the Quality Department.

¹¹ Exhibit P-0042, p. 50.

Accountability for quality of care and service rests with the Program/Department Leadership and staff. A formal structure will exist to ensure that:

- a comprehensive quality plan is in place,
- evaluation is ongoing,
- evidence based practice is pursued,
- results of evaluations are analysed,
- improvements are undertaken to address priority areas identified.

Formal structures include Internal Advisory Committees, peer review activities, External Advisory Committees, indicator monitoring and quality improvement activities. Accountability is to the applicable Vice President. Quality reports will be reviewed in detail within the Department/Program before being presented to Corporate Team.¹²

In addition to departments and programs, there were a number of corporate committees which also had responsibilities in this area. Examples include the infection control and occupational health and safety committees.

After review by the applicable vice-president, reports would be forwarded to a Corporate Quality Initiatives Committee comprising the corporate team (executive) and a Director of Quality Initiatives. All programs, departments, professional practice groups, and specified committees were accountable to this committee, through an annual report. The Corporate Quality Initiatives Committee was directed to provide feedback and recommendations following review of the annual reports. In addition, there was a Quality Initiatives Committee of the Board of Trustees. Its role was to receive reports from the CEO regarding quality issues and in turn to report to the full Board of Trustees. This policy continued until January 2007, when Eastern Health introduced a new policy: *Quality and Risk Management Framework*¹³. It is planned that the *Quality and Risk Management Framework* will be revised again when a new computerized system of reporting occurrences,¹⁴ presently under development, has been finalized.

¹² Exhibit P-0042, p. 12.

¹³ Exhibit P-0058.

¹⁴ An occurrence is, "Any event, accident, error, or circumstance that is not in keeping with expected process or outcome of care or service."

The *Quality and Risk Management Framework*, which was last updated in June 2007,¹⁵ is more policy-oriented than the document it replaced. It adopts the Canadian Council on Health Services Accreditation (CCHSA)¹⁶ definition of quality: “the degree of excellence; the extent to which the organization meets client/patient/resident needs and exceeds their expectations.” It identifies six groups within Eastern Health that have responsibility in the area of quality improvement and risk management. These are:

1. Board of Trustees Safety and Quality Improvement Committee
2. Regional Quality Council and its Subcommittee Structures
3. Portfolio Quality and Safety Committee and its Subcommittee Structures
4. Quality and Risk Management Department
5. Program and Department Leadership Teams, and
6. Quality Improvement Teams.

At the end of the document there is a list of programs and processes for quality improvement and risk management. Included in that list are accreditation, claims management, morbidity and mortality rounds, occurrence reporting and analysis, peer review activities, performance appraisal, performance reporting, policy and procedure manuals, quality committees, quality improvement teams, quality reviews, risk management, risk self-assessment and sentinel event reviews. The *Quality and Risk Management Framework* does not change the basic concept that the programs and departments are primarily responsible for the development and updating of quality initiatives within Eastern Health, as they had been within Healthcare.

In summary, from April 1999 onward, Healthcare had formally identified quality initiatives as a part of the activities of each department or program, including the laboratory medicine program. A Quality Department had been tasked with assisting the development of quality

¹⁵ On the basis of the information available to the Commission on the close of hearings, October 31, 2008.

¹⁶ Now called Accreditation Canada.

planning. The Board of Trustees of Healthcare had seen quality to be of sufficient importance to warrant the creation of a committee of the Board devoted to the issue. For these steps in support of patient safety, Healthcare's leadership is to be commended. To answer the questions raised by the Terms of Reference, I propose to examine the quality systems in place within the laboratory medicine program at Healthcare, as they relate to ER/PR testing, from 1997 to 2005. I will also examine the procedures in place for the reporting of occurrences. The corporate-wide policies regarding disclosure will be examined under the sections of this report that examine communications.

Quality Assurance, Quality Control, and Risk Management

The concepts of quality assurance and quality control are not new, nor are they unique to health care. There is, however, a heightened awareness of their importance in the context of the patient safety movement. There are numerous definitions of each and on occasion the terms are used interchangeably. It is with some temerity that I risk adding to the confusion by providing a definition of quality assurance and quality control as used in this report.

Quality control is a system of routine techniques and activities used to control the quality of the product being produced or service being provided. Quality control activities might include archiving data and, in the laboratory setting, using positive and negative control specimens, and checking temperatures of water baths or paraffin wax.

Quality assurance is a system designed to review procedures used by those who regularly perform a service or create a product with the goal of ensuring that standards have been met. In the laboratory setting, quality assurance could include a second testing of a percentage of slides, proficiency testing by an independent body, or a review of documentation by the quality department of a hospital. Quality assurance, which may be carried out by persons from another division of the same organization or by an independent body or person, examines the results of quality control.

In my opinion, it is imperative that quality control and quality assurance be an integral part of all patient care functions performed in any hospital laboratory.

Risk management is another term that is frequently used in the context of health care, though, once again, it is not confined to that field. The goals of risk management are to identify and assess the risk of negative occurrences, and to develop strategies to avoid, mitigate, transfer, or accept the risk. The work of a risk manager can be proactive or reactive. Insurance, for example, would be a way of transferring the financial cost of a risk. If an organization chooses to accept a risk, that organization would be expected to budget for such an occurrence.

Quality Control and Quality Assurance at Healthcare Laboratories

As noted above, Healthcare had a Quality Department whose functions included risk management and the promotion of quality assurance measures, but it had no responsibility for the development of quality systems within the laboratory. It could have a role in investigating occurrences, when they were reported, and in identifying risk. Ms. Predham, who had been the risk manager with Healthcare from 1998,¹⁷ described her role as risk manager as including education of staff on quality-related policies, co-ordinating the entire quality facilitator program, supervising the facilitators, investigating complaints, and liaising with the insurer and with legal counsel. Some of those functions are, at present, performed by the claims manager,¹⁸ who is responsible for liaison with the insurer and the investigation of the claims for insurance purposes. The claims manager reports to Ms. Predham.

The program director and clinical chief of laboratory medicine were accountable for quality within the Laboratory Medicine Program in Healthcare, though, I hasten to add, there was a role for technologists and pathologists in ensuring quality. The difficulty here is that at the relevant time there was no meaningful articulation of roles of any

¹⁷ Ms. Predham's position is now titled "risk management consultant."

¹⁸ The position of claims manager was only recently created.

personnel, vis-à-vis quality, beyond those of the leadership team¹⁹ specified in the quality plans discussed above.

A comprehensive quality plan in a medical laboratory must include quality assurance and quality control measures. Written policies and procedures are essential. There must also be a system for periodic review of the policies and procedures to ensure “evaluation is ongoing” and “evidence-based practice is pursued.” In my opinion, quality assurance and quality control measures are simply good science and should have been included in standard laboratory practice whether *Implementing a Quality Plan* existed or not.

Over the years, efforts to develop or improve quality control and quality assurance programs within the pathology section of the clinical laboratories at Healthcare seemed to proceed at a snail’s pace. The performance goals and objectives form for the clinical chief for the year 2002/2003 serves to illustrate the point. The form states a goal and then the progress made on January 1, April 1, July 1, and October 1, 2003. One goal was “quality control policies and procedures manual for anatomic pathology and cytopathology.” The note for January 1, 2003 states “First draft completed for review by Leadership Team of Anatomical Pathology. Dr. Carolyn Morris-Larkin reviewing Q.A. Program for Cytopathology.” On April 1, the note said: “second draft has been completed and out for review. Ongoing.” There was no comment for July 1. For October 1, the entry was: “This is progressing. Feedback received on draft and after revisions, it will be circulated more widely in the Program.”²⁰ The matter of developing a quality control policies and procedures manual did not reappear the next year in the performance goals and objectives of the clinical chief.

¹⁹ One of our witnesses used the phrase “motherhood rhetoric” to describe a job description for a clinical chief that he had been given by Eastern Health. The job description contained in Dr. Cook’s appointment letter could also be characterized in that way. If that was the only standard by which to assess a clinical chief’s activities in the area of quality initiatives, one would be at a loss to do so.

²⁰ Exhibit P-1570, p. 5.

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Dr. Sushil Parai was site chief, Grace Hospital, from 1996 to July 2000, prior to becoming site chief at the General Hospital, a position he held until March 2005. Dr. Parai recalled that in 2001 they began development of a “quality control/assurance program” for the clinical component of the pathology laboratories at Healthcare. That document went through four or five revisions between 2001 and 2004, but was not implemented by the leadership team of the laboratory medicine program. In fact, Mr. Terry Gulliver did not recall having seen the document prior to his testimony at the Inquiry. Dr. Parai gave the then existing draft to Dr. Beverley Carter when she became chair of the Quality Assurance Program around the end of 2004.

Within weeks of Dr. Carter’s obtaining a permanent position with Healthcare in August, 2004, Dr. Donald Cook asked her to establish a quality control and quality assurance committee within anatomical pathology. Dr. Carter understood that no such committee had existed prior to August 2004. A central feature of the work of this committee, as proposed by Dr. Carter, was to be monthly reviews, with reports being generated for the committee that would then be forwarded to specified individuals. The proposal included such quality assurance measures as random reviews of two percent of surgical pathology cases each week, and frozen section reviews. Technical issues would also be addressed. The development of a policy and procedures manual was identified as part of the committee’s task. The first meeting of this committee was held in November 2004, at which time it was decided to give priority to the monthly reviews. Soon after the first meeting, Dr. Gershon Ejeckam, a pathologist, resigned from the committee and others had to be recruited in his place. One of the members of the committee described it as having done good work but conceded that in the end there were no policies or procedures produced by the committee. By the spring of 2005, the ER/PR problem had begun to supersede every other issue.

In 2003, as a means of improving communications between pathologists and technologists regarding technical issues, a log book was placed in the General Hospital reporting room, where the pathologists read slides and dictated their reports. This gave the pathologists an opportunity to note any problems they observed so that any such issues

could be addressed. Very few entries were made in the log book and it quickly fell into disuse.

On the technologists' side, there was no "formal" quality assurance or quality control system as of January 11, 2005. Ms. Peggy Welsh was a technologist at the General Hospital from 1977 to 2003. From the mid 1980s, when immunohistochemistry (IHC) was first introduced to the laboratory, she was involved. She recalled the introduction of ER/PR to that section of the laboratory in 1997. She stated that there were no quality assurance measures in place during the time she worked in IHC. There certainly would have been activities related to quality control, such as checking of temperatures of water baths, or the running of external controls, but these were not always recorded.

There were no policy and procedures manuals in the IHC laboratory. The only documents referred to by technologists as having been provided for their guidance in performing ER/PR testing were manufacturer's specifications, which accompanied the DAKO Autostainer and the Ventana Benchmarks, the manufacturer's specification sheets (spec sheets) for various antibodies, and a guide for peroxidase anti-peroxidase (PAP) testing that had been produced within Healthcare when IHC was a totally manual process. The "PAP guide" was described by Ms. Welsh as representing the amended procedure that was adopted when one pathologist returned from a sabbatical in France.

It is essential that a laboratory have precise, clear, written instructions for technologists performing tests. These must be kept current and there must be protocols to ensure that all technologists become aware of any revisions to a manual.

It was implied in the testimony of some witnesses that in a small laboratory the necessity for manuals was somehow less because so few people were doing the tests and they were all very familiar with the protocols and procedures. The fallacy in that reasoning was demonstrated by the evidence of one of the two laboratory technologists who were the first to do ER/PR testing using IHC. In the ER/PR testing method used at Healthcare, heat was applied to slides at the antigen

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retrieval stage of the process. When testing was performed using a manual procedure, the technologists used a hot plate for heat-induced antigen retrieval. Though that aspect of ER/PR testing continued to be essentially a manual one, a water bath was introduced to aid in the maintenance of a constant temperature. As to how long slides should be left in the water bath, Ms. Mary Butler, a laboratory technologist, said that since the spec sheets from the antibody manufacturer said 20 to 40 minutes, she used 30 minutes for the slides she processed. On the other hand, Ms. Welsh said the slides would be immersed in heated water for a period of 20 to 30 minutes: "I'm not exactly sure any more what the timing was." Mr. Les Simms, a laboratory technologist, who commenced work in the IHC section of the laboratory at the General Hospital in March 2003, recalled that he would heat the slides for 20 minutes, which figure he learned from Ms. Welsh and which he "assumed was their optimum procedure."

Of course, there should have been validation of the antigen retrieval process in of ER/PR testing, which should have included a determination of the exact period of time slides should be in the water bath.

While validation was said to have been done, the absence of records of validation procedures became problematic during the investigation of the ER/PR problem. This was true for both the DAKO Autostainer and the Ventana Benchmarks.

Ms. Trish Wegrynowski's report noted deficiencies in the area of quality assurance. She said:

Currently neither External Quality Assurance nor Inter-Laboratory comparison (excluding Mount Sinai Hospital Retrospective analysis) is performed. No documentation was seen concerning Internal Quality Assurance for both the Technical and Professional components.

You need to ensure the quality of your Laboratory's results to determine the accuracy and reliability of the procedure. There must also be a mechanism to

evaluate the inter-observer variability amongst all the Pathologists interpretation of IHC staining.²¹

Ms. Wegrynowski made several recommendations, including:

1. Membership in the College of American Pathologists peer assessment/education program and peer performance programs,
2. Inter/Intra laboratory comparison between St. Clare's and General Hospital pathologists,
3. Proficiency testing and inter-laboratory testing,
4. Development of an IHC user group, and
5. Provision of opportunities for technologists to attend medical rounds relevant to their work to understand the larger scope of practice.²²

There is no suggestion that the Corporate Quality Initiatives Committee was ever advised of deficiencies in the Laboratory Medicine Program's quality initiatives for the period 1997 to 2005. For example, there was no external proficiency testing for the IHC portion of the laboratory during that period. The Corporate Quality Initiatives Committee was not advised of that. Within days of his discovery of the ER/PR problem and before its scope was known, Dr. Cook recommended to Dr. Robert Williams that they immediately establish an external proficiency testing and monitoring program for immunoperoxidase testing. This is an explicit acknowledgement of the absence of this type of quality assurance prior to that date. In his testimony Dr. Williams recalled that Dr. Cook described IHC as "like an island in the sea," meaning that it was an area of the clinical laboratory where quality assurance measures that were in place in other parts of the laboratory were missing. Dr. Williams stated that he had assumed that external proficiency testing was in place and he understood that Dr. Cook was also ignorant of the absence of such testing.

Dr. Cook's testimony emphasized a somewhat different point. Dr. Cook stated that he saw IHC as being included in the quality programs

²¹ Exhibit P-0047, p. 17.

²² Exhibit P-0047, p. 17.

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for the division of anatomical pathology. As he put it, if pathologists “refer cases out for an outside opinion, most cases there were IHC slides included or paraffin blocks for IHC, so in that way the IHC was incorporated into the – our quality assurance programs for the division of anatomical pathology.”²³ The laboratory participated in the College of American Pathologists Performance Improvement Program for anatomical pathology and cytology and in a proficiency testing program with the American Society of Clinical Pathologists. Pathologists participated in Continuing Medical Education (CME) activities, rounds, and reviews of work by other laboratories, but none of these were directed specifically to IHC. Dr. Cook agreed, however, that his view of the need for quality assurance for IHC changed after the ER/PR problem arose.

I agree with Dr. Cook’s view that quality control and quality assurance in histology are part of quality control and quality assurance for IHC, but he and I have a somewhat different perspective on the point. Dr. Cook’s point is that if you were doing referrals to other laboratories for other purposes, the ER/PR slides could be included with those sent and, therefore, they too would be reviewed, though that might not be the object of the referral. If and when that occurred, it would be quality assurance by chance, not by design.

The information available to this Commission demonstrates clearly the importance of accuracy at all stages of testing, from handling of the fresh specimen to the reading of the slides. The repeated references to fixation and processing problems in the production of ER/PR slides from 1997 to 2005 underscore this point. My conclusion is that to ensure proper procedures for ER/PR testing one must ensure proper procedures for fixation and processing of tissue and production of slides. I would add that fixation and processing are not unique to IHC testing.

Dr. Cook’s opinion was that budget restraint over the years had contributed to the problem, as had the management structure introduced to the laboratory by Healthcare. There was a reduction of the number of managers in the laboratories within Healthcare over the years,

²³ Transcript of testimony, Dr. Donald Cook, July 3, 2008, p. 244.

particularly after the Hay Group *Operational Review of the Health Care Corporation of St. John's* in March 2002. Dr. Carolyn Morris-Larkin, a pathologist, recalled budget cuts reducing the number of journals available to pathologists and causing the elimination of teleconferences from the American Society of Clinical Pathology. She also believed that pathologists were discouraged from sending cases for external consults for this reason. A program was set up whereby referrals were reviewed before being sent to an outside laboratory. So long as the cost of the referral was not a determining factor in deciding if a referral should be made, I do not see such a step, in itself, as being necessarily a bad thing. Dr. Cook saw the updating of policies and procedures and monitoring of quality control activities in a laboratory as part of the job of a manager. He saw the program management model, as applied to the laboratory, as resulting in confusion as to who controlled what. On the latter point, Dr. Diponkar Banerjee was of a similar view. I agree that budget restraints contributed both directly and indirectly to the problems in the laboratory, and that the organizational structure of the laboratory did not promote resolution of the problems. However, the history of failed attempts to produce even a policy and procedures manual for ER/PR demonstrates that these were not the only factors contributing to the ER/PR problem.

The efforts of the program director and the program manager for pathology in the period prior to 2005 emphasized improvement of technology. The introduction of the Ventana Benchmark, a fully automated machine, lessened the potential for human error that had so marked the introduction of the ER/PR test and continued to be present with the DAKO Autostainer. However, as the earlier discussion has indicated, it is not sufficient to purchase a machine, set it up in a laboratory, and start testing. There is a very important validation process that must take place before such an instrument is used in testing and during which decisions must be made about such things as concentrations of solutions and timing of certain steps. The resulting protocols must be put in writing and strictly followed in the processing of specimens. While these instruments were an improvement on manual processing and lessened the opportunities for human error, they could not resolve problems with quality. Mr. Bryan Hewlett and Mr. William

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Parks made this point accurately and succinctly in their report to this Commission:

The implementation of new technologies requires much more than purchasing new instruments. It requires a strong core group of experienced technologists with intimate knowledge and deep understanding of the current technology and willingness to learn and apply the new technology. The application of any new technology without this experience, knowledge and understanding can have dire consequences.²⁴

Testimony throughout the Inquiry repeatedly emphasized that IHC testing is an intricate process. The failure to ensure quality control and quality assurance directed to IHC specifically was, in my opinion, a serious flaw in the management of the anatomical pathology division of the laboratory. The concepts were apparently well established in other areas of clinical laboratory medicine. Quality control and quality assurance within the IHC laboratory itself during the period of 1997 to 2005 were so little and so haphazard as to be non-existent.

External and Internal Controls: ER/PR Testing - 1997 to 2005

“Quality means doing it right when no one is watching.” - Henry Ford

Both external controls and internal controls must be a part of any quality control system for ER/PR testing. Generally speaking, the position of Mr. Gulliver and the technologists who worked in the IHC section of the laboratory was that external positive controls were always run with ER/PR tests done between 1997 and 2005. All agree that no negative controls were run throughout that period. There was no method of identifying which external positive control related to which slides, unless the external control slide happened to be filed with a particular patient tissue slide. Occasionally, a technologist might note on a requisition form the fact that an external control was run, and sometimes in reporting the testing results a pathologist might refer to the external control. There was no systematic record maintained of the use of external positive controls. Both technologists and pathologists recognized the importance of using external positive controls.

²⁴ Exhibit P-3119, p. 8.

After an introductory period when Dr. Mahmoud Khalifa read all ER/PR slides, a policy was adopted that ER/PR slides for any given patient would be read by the same pathologist who had interpreted all the other slides related to the case. This change seems to have come at the instigation of the St. John's pathologists. The pathologists from outside St. John's, who were generally content with Dr. Khalifa continuing to read ER/PR slides, were not consulted. They were merely informed that the slides would be returned to them for reading. Pathologists working in smaller hospitals in Newfoundland and Labrador would rarely be involved with IHC testing. This is because the work is primarily done in the General Hospital and IHC tests are generally ordered by specialists, most of whom work in larger hospitals. Consequently, the reading of IHC tests is largely a matter for pathologists working in St. John's hospitals.

All ER/PR testing was done at the General Hospital. A patient from Gander, for example, would have the diagnosis of malignant carcinoma of the breast given by a pathologist in Gander hospital. A block would then be chosen by that pathologist and sent to the General Hospital for ER/PR testing. Following the completion of the tests, the IHC slides would be returned to Gander for interpretation. Sometimes an external positive control slide might be sent to Gander as well. Sometimes there would not be sufficient external control slides to provide one to every hospital having slides in a particular ER/PR run. While Dr. Khalifa was still at the General Hospital, he undertook to read all external control slides and ensure that those controls had worked properly before the patients ER/PR slides were returned to the other hospitals. Some pathologists were content with this arrangement; others were not. Some pathologists believed, incorrectly, that this system continued after Dr. Khalifa left.

This system of ER/PR reporting had a number of obvious difficulties. One was that the number of ER/PR tests read by individual pathologists in any year could be quite low. It was generally agreed by experts in the field that to maintain competence in ER/PR testing it is necessary to perform a certain number of tests per year. The view of the appropriate number varied but none would have been as low as the

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numbers seen by the pathologists in St. Anthony or Grand Falls, for example. Dr. Banerjee opined that ER/PR slides should be read by pathologists working at the laboratory where the staining is being done. He also opined that the senior medical director of IHC for that laboratory should be able to troubleshoot. These two points form the basis for Dr. Banerjee's recommendation that all ER/PR testing be done at one location where a small number of pathologists would read the slides.

From 1997, when ER/PR testing was introduced at the General Hospital, to 2005, not all pathologists in Newfoundland and Labrador were aware of the importance of internal controls in ER/PR testing. Fifteen pathologists who had practiced in Newfoundland and Labrador during all or a portion of that period testified before the Commission. Whether a pathologist paid attention to internal controls depended on where and when he or she did pathology training and whether he or she had a particular interest in IHC. Generally the pathologists could be divided into three groups: those who were not aware of the role of internal controls in ER/PR testing until Dr. Ejeckam's memo of May 2, 2003 (if they received that memo), those who were aware that there was a role for internal controls but focused almost exclusively on external controls, and those who were aware of the importance of internal controls and used them in making decisions about the validity of results. Once the first group learned about internal controls, most of them seemed to have moved into the second group.

In this Inquiry, the two pre-IHC steps that have garnered attention are fixation and tissue processing. Time and again the expert witnesses emphasized the importance of these early stages, particularly fixation, in the production of a valid result. Dr. Banerjee noted that, "as a general rule, if the tissue hasn't been well fixed and well processed, no matter what you do subsequent to the tissue being processed, in terms of special stains or immunohistochemistry, the results will not be optimal and even the morphology of the cells are distorted so that it may be difficult to actually identify the cancer type or whether there's cancer or benign tissue in there, particularly with smaller biopsies."²⁵

²⁵ Transcript of testimony, Dr. Diponkar Banerjee, July 30, 2008, pp. 95-96.

Accreditation Surveys

There was consensus that the accreditation surveys conducted by the CCHSA (now Accreditation Canada), in which Healthcare and Eastern Health regularly participated, do not provide a solution for the lack of quality assurance within laboratory programs. Indeed, Dr. Williams indicated that this deficiency was recognized by the Corporate Quality Initiatives Committee in 2004. CCHSA surveys, even with a recent move to improve the laboratory portion of the survey, are not sufficiently rigorous to provide the kind of information that is needed to ensure quality practices within laboratories.

There are, however, in other provinces, requirements for laboratory accreditation. These requirements are linked to the licensing of laboratories. One example of this is Quality Management Program – Laboratory Services (QMP-LS) in Ontario, which at the request of Eastern Health performed an “on-site consultation” of the IHC laboratory at the General Hospital in December 2007.

It was suggested in testimony that the establishment of a requirement for participation in an accreditation process directed to laboratory service is under active consideration by the Department of Health and Community Services. In my view, such a requirement would assist laboratories both in the establishment of standards and in their rigorous enforcement. I recommend that such a step be taken. It is not for me to suggest the precise method of implementing the recommendation. It may be possible to contract with an established group to perform these services; it may be that a co-operative effort by a number of provinces would be the most efficient method of ensuring that the service is available in Newfoundland and Labrador. All clinical laboratories should be required to participate in an accreditation process specifically directed to laboratory practice. It is important, however, that those doing the accreditation be independent of the Newfoundland and Labrador Regional Health Authorities. Because there are relatively few technologists and pathologists involved in laboratory medicine in Newfoundland and Labrador, effectively this means that the persons doing accreditation must come from outside the province. If credibility is

to be restored to clinical laboratory pathology here, those assessing performance must be and must be seen to be independent.

The Team

It is clear that the technologists who worked in the IHC section of the laboratory did not feel that they were members of a team. Many of their complaints could be said to result from the organizational structure of the laboratory, which is discussed elsewhere. For example, they were concerned about conflicting instructions from pathologists, how to determine priorities when they were getting demands from more than one pathologist, and to whom they should look for assistance. Interestingly, these frustrations, which were first identified by Ms. Predham in the summer of 2005, seemed to come as a surprise to Dr. Cook and Dr. Williams. Ms. Predham encountered such sentiments when she again surveyed the technologists on May 29, 2007.

Certainly technologists and pathologists have separate roles, but their activities are interdependent. Between 1997 and 2005, there were from time to time pathologists who worked closely with the technologists and who developed a relationship with them, a relationship that included educating technologists on testing and being readily available to provide advice. However, on the whole the relationship between the two groups did not contribute to team building. There seems to have been little true consultation at the leadership team level or otherwise. Each group made incorrect assumptions about the other. For example, the technologists believed that when the pathologists read the slides they provided a quality assurance role for the technologists' work; the technologists felt that if there were problems, the pathologists would say so. The pathologists were not aware that the technologists had this understanding and did not see themselves in that role. A pathologist might, from time to time, comment on the quality of a slide. This was not done from the perspective of maintaining the highest quality. Rather, the pathologist wished to ensure that the quality of the slide was sufficient to allow it to be read. The first looks at maintaining the highest of standards, the second looks at whether a minimum standard has been met. The absence of a team perspective was reflected in the actions of the pathologists and technologists before the revelation of the ER/PR

problem, and in their reactions after the problem was revealed. This situation also illustrates the danger of “informal” quality assurance and quality control procedures.

When one compares what actually occurred within the IHC laboratory against the goals and processes outlined in *Implementing a Quality Plan*, one can only conclude that there was a complete failure to develop a quality plan for IHC, specifically ER/PR testing. There was no clear line of responsibility for ER/PR testing. There were periods when Dr. Khalifa or Dr. Ejeckam was seen by the technologists as the “go to” person for IHC, but in their absence that person seemed to be whichever pathologist a technologist could find. There were no procedures manuals for IHC testing. There was documentation of requisitions for ER/PR tests and test reports, but there was no consistent recording of activities within the IHC laboratory, including whatever validation procedures were carried out.

Education and Training

Laboratory Technologists

The Laboratory Medicine Program of Healthcare was divided into six divisions: biochemistry, haematology, microbiology, cytology, pathology, and immunology/genetics. Most technologists in Healthcare’s laboratories graduated from a course at a technical college that provided training in all of these areas. Following that training and a period working in a clinical setting, there would have been a national exam set by the Canadian Society of Laboratory Technologists, now called the Canadian Society for Medical Laboratory Science, the certifying body for medical laboratory technologists. Today, a successful candidate would receive the designation of medical laboratory technologist (MLT). In an earlier time, the designation would have been registered technologist (RT).

While formal training provides technologists with the basics, no one suggested that training was sufficient to work in IHC. Further, it was agreed that training to work in IHC would normally occur on the job rather than in a school or college.

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Within a laboratory, training of a technologist in IHC might include formal and at-the-bench training. The number of IHC tests performed varies greatly from laboratory to laboratory and that would obviously influence the time required for training. Mr. Parks, the charge technologist at the histology laboratory at The Ottawa Hospital, who is very involved in training at that institution, noted that as a prerequisite to training in IHC one must be competent in all aspects of histology. At The Ottawa Hospital, candidates must write an exam in histology before being admitted to IHC training. He further noted that IHC technologists within that institution must, on a regular basis, rotate back into histology for a period of time to keep up their skills. In addition, when new stains are introduced or new techniques are adopted in IHC, there is training, and each technologist is assessed yearly for competency, even those with years of experience.

Mr. Hewlett observed that if the number of IHC stains being used in a laboratory was only about half a dozen then with a good histology background the candidate might complete training in IHC within a few months. For 300 stains he opined that training would take at least a year because a technologist must become familiar with all of the expected actions and cross-reactions for each test performed.

Ms. Wegrynowski stated that at Mount Sinai it would take about a year for the completion of the IHC training so that a technologist would be permitted to work independently. Sometimes that period might be lessened by some months if the trainee had had years of experience in another area of the laboratory and was already familiar with some of the essentials for IHC testing. Even then, the training period would not be less than six months. Ms. Wegrynowski also agreed with Mr. Parks about the need for competency assessment. She opined that current and new staff should be assessed for competence to perform tasks, identify requirements of a task, perform gap analysis, and develop action plans. Ms. Wegrynowski's view was that this was a patient safety issue.

What must be obvious from the testimony of these three experienced technologists is that quality is costly. The education and

practice described by Mr. Parks, Mr. Hewlett, and Ms. Wegrynowski are time-consuming.

Each technologist from Eastern Health, with the exception of the first to do IHC testing, had been trained in IHC testing by a predecessor. When ER/PR testing was introduced, Ms. Welsh worked with Dr. Khalifa, assisting in his validation process, and learned about ER/PR in that way. Generally, training in IHC at the General Hospital involved two to three weeks of working with a technologist experienced in IHC. At present, ER/PR testing is only one of over a hundred tests performed in the IHC laboratory at the General Hospital.

It is also helpful to note the rigid training requirements Ms. Maria Tracey discussed in her testimony related to nurses in the operating room. These are in stark contrast to requirements for laboratory technologists. The requirements for operating nurses, particularly the strict compliance with policies and procedures, examination after orientation is completed, and the possibility of prolonging orientation or preventing staff members from working in the operating room if their skills are not up to the standards required for operating nurses, were developed with safe patient care as the goal²⁶. A similar approach should be applied to laboratory technology staff, as these positions are also extremely important to safe and accurate patient care.

In my opinion the training in IHC provided to the technologists at the General Hospital was sadly lacking. To their credit, some tried to supplement their training by reading texts or articles. It was quite startling during the testimony of Ms. Welsh to hear her explain that during the time she was working at the General Hospital she believed that she was fully trained. However, referring to the testimony at the Inquiry hearings and particularly that of Ms. Wegrynowski, she candidly said:

I've learned a lot in the last month that I had never heard in all the time I was doing the work.

²⁶ Transcript of testimony, Maria Tracey, September 30, 2008, pp. 27-29.

The training did not equip the technologists to handle all aspects of the job. For example, there was an obvious weakness in the ability to troubleshoot.

In her report, Ms. Wegrynowski made a number of observations regarding deficiencies in education for technologists and suggestions for improvement. She noted the absence of textbooks in the laboratory and the internet at the workbench. She suggested that funding be made available for histotechnologists to attend lectures and workshops devoted to IHC, particularly those available through the National Society of Histotechnology.

In his October 17, 2005 report, Dr. Banerjee referenced the work of the technologists when he listed “other system flaws observed.” Of particular relevance to the technologists were the following:

1. Lack of dedicated immunohistochemistry technologists. A rotation is used. This prevents the technologists from gaining in-depth expertise in troubleshooting.
- ...
6. Attendance by both medical and technical staff at various conferences with a focus on new technology should be encouraged. Consensus-driven innovation should be the goal.

It is essential that technologists, like pathologists, maintain and improve their knowledge and skills once the formal training is completed. Competency testing should be carried out on a regular basis to ensure that skills are always consistent with the laboratory’s requirements. Many of the experts before the Inquiry identified the need for dedicated staff in IHC. That particular recommendation was accepted by Eastern Health some time ago, as was a recommendation for pathology assistants. However, the investigation of the ER/PR testing problems highlights the interdependence of different aspects of the laboratory. IHC testing involves slides, cut from blocks, prepared from specimen samples taken from patients. Everything that occurs prior to the creation of a slide can and does affect the quality of the end product. The competency of the technologists and pathology assistants who contribute to the production of the slide used for ER/PR testing is also vital. In many provinces technologists must be licensed. Licensing

would provide the benefit of setting professional standards and creating greater opportunities for continuing education for technologists.

The Pathologists

When the pathologists other than Dr. Khalifa began to read the ER/PR slides, no formal training was provided for them. Dr. Khalifa did advise other pathologists that “educational” slides were available for viewing if they wished. IHC is a small part of the education of pathologists and for most pathologists a very small part of their workload, though there may be hundreds of IHC tests performed in a laboratory. Unless a pathologist had done relevant subspecialty training, it is unlikely that he/she would have had much exposure to ER/PR testing.

The Commission was advised that there are in development a number of other tests like ER/PR, whose results will be used as either predictive or prognostic markers and will be relied upon to stratify patients for appropriate therapies. This makes it all the more important that the lessons from the ER/PR problem not be lost.

The experience with ER/PR raises the questions of how one ensures that those who are reading the slides are competent to do so, and whose responsibility it is to ensure that level of competency. Newfoundland and Labrador pathologists said, in effect: we train ourselves. We read the literature on the subject, we attend seminars and see the pictures of what the slides should look like and make a judgment call. If one is lucky, a pathologist might be able to attend a conference where the subject is being discussed. The ER/PR issue is proof that this approach to training for subspecialty work has its limitations.

It is basic that the competency of persons working within the laboratory and providing services to regional health authorities is the responsibility of each institution. Therefore, prior to the introduction of new tests, there should be a procedure to ensure that all persons participating in the process, whether the technologist processing the tissue and slides or the pathologist reading the slides, are competent to do so. Leaving it to individuals who are already busy to research and

train themselves did not work for ER/PR. I have no confidence it will work for other IHC tests to come. Before a new test is introduced, a process of education should be undertaken, and some person must be accountable for that having been done before the test is offered to patients.

Dr. Banerjee's report on the immunohistochemistry service at Eastern Health was sent to Dr. Cook on October 17, 2005. In the accompanying letter Dr. Banerjee noted other issues that he felt had a bearing on "the sustainability of a quality laboratory program." It was Dr. Banerjee's view that to attract and retain the best pathologists,

Pathologists' compensation should be competitive with those of other provinces, otherwise your department will face ongoing staff turnover as pathologists move to more rewarding positions elsewhere. Unless this "revolving-door" syndrome is dealt with, it will only lead to deterioration of the quality of staff as you will continue to lose your best people.

For a high quality cancer program in the province, your department must invest in subspecialization, continuing education, and central pathology review for the entire province, in order to provide the highest quality of service and cancer diagnosis, so that your oncologists can manage their patients optimally. All cancer patients deserve the same standard of care regardless of where they live. Accurate pathology diagnoses, grading and staging are essential for clinical decision making and these activities cannot be compromised.²⁷

The issue of compensation for pathologists in Newfoundland and Labrador was addressed by the Government while the Inquiry hearings were in progress. Consequently, I shall make no recommendations regarding the question of compensation. I would add that I agree that the level of compensation was a factor in the ability of the province to attract pathologists during the period from 1997 to 2005 and, equally important, the ability to retain pathologists who came to work in this province. Pathologists are in short supply. That is not unique to Newfoundland and Labrador. There have been and will always be opportunities to work elsewhere. Rapid turnover of pathologists did have a negative impact on committee work in the St. John's hospitals, which is where the

²⁷ Exhibit P-0046, p. 1.

development of policies and procedures within the laboratory was intended to be done.

The question of subspecialization of pathologists is relevant to the past and the future. In the past, there was a reluctance in the St. John's hospitals to develop subspecialization within pathology. This was because of the turnover rate of pathologists. It was felt that all pathologists had to maintain all skills because of the likelihood that the one or two subspecialists in, for example, breast pathology might not stay, and then those who remained would have to pick up that work again. While that was perhaps a natural reaction to what had been occurring for years, the failure to subspecialize resulted in a greater disadvantage. After the discovery of the ER/PR problems, Eastern Health changed its position respecting subspecialization for breast cancer. Subspecialization was one of Dr. Banerjee's recommendations in his report of October 17, 2005.

When Adverse Events Happen

Occurrence Reporting

A method for recording and classifying adverse events is essential to any quality assurance program. Ms. Predham was able to cite examples of situations in which a reporting system enabled the Quality Department to identify a pattern of error and thereby take corrective action and prevent further adverse events. In 2007, when a new Occurrence Reporting policy was developed for Eastern Health, its purpose was said to be to:

- Provide a database of clinical safety issues and the corrective actions taken;
- Promote consistency and timeliness in reporting occurrences;
- Facilitate response by the Quality and Risk Management department to potential liability exposure;
- Monitor, track and trend so that high priority areas for improvement can be identified and actioned and reoccurrences prevented;
- Use as a tool in the improvement of the quality of patient/client/resident care;

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- Provide opportunities to provide feedback, dialogue and problem solve.²⁸

While this was a 2007 statement, the same statement of purpose could have been made in 1997.

In 1997, Healthcare implemented a policy on occurrence reporting. The portion applicable to patients defines an occurrence as “any event, accident, error or circumstance which is not in keeping with expected process or outcome of care or service. Occurrences may result in an injury to an individual, damage or loss of equipment or property.” Any staff member who observed or discovered an occurrence has an obligation to “initiate an Occurrence Report.” Ms. Predham was clear that an occurrence could be something that did not actually reach the patient. The 1997 policy included specific instructions on completion of the form, including an admonition to record only factual information and not to express personal opinion, find fault, or lay blame. Occurrence reports were not to be placed on the patient’s health record, nor was the fact that there had been an occurrence report filed to be noted on the patient’s chart. As Ms. Predham described it, an occurrence report is not part of the health record, nor part of the clinical process; it is a quality assurance activity. Occurrence reports were and are considered by Eastern Health to be protected under the *Evidence Act*.

The 1997 policy specified who was to be notified of an occurrence: “in charge person, manager, attending physician or Clinical Chief.” The form was to be sent to the “Program/Department Director/Clinical Chief for further action.” That person was to forward a copy of the report to the appropriate person in the Quality Department within 48 hours. The policy made the leadership team of the program or department concerned the first line of investigation and follow-up with patients. It also required the filing of a follow-up form to record the action taken. The role of the Quality Department was to monitor reports, retain forms, assist where asked with investigation and loss-control activities of significant occurrences, and assist in identifying, controlling or preventing risk. The risk manager’s job included liaising with the insurer and/or legal counsel.

²⁸ Exhibit P-0057, p. 7.

Within Healthcare, there was also, from 1999, a Critical Occurrence/Incident Review Policy. This specified a process for dealing with occurrences of a particular class. Essentially, a critical occurrence was something of such significance that it would require immediate reaction. Ms. Predham illustrated those circumstances: “if somebody – a patient is severely harmed or there’s a potential that you think that the patient may be harmed...”²⁹ Generally, the procedure for critical occurrences included more involvement of executive above the program leadership team and required the risk manager or another person from the Quality Department to participate in determining the process for investigation of the occurrence.

There was debate about whether the events of 2005 related to ER/PR testing constitute one large occurrence or hundreds of occurrences, but there was acceptance that it came within the definition of “occurrence.” With one exception, no one within Eastern Health believed that an occurrence report was submitted on ER/PR. Dr Williams saw the May 24, 2005, letter from Dr. Cook to himself as an occurrence report. Dr. Williams acknowledged that there was a form for occurrence reports, but argued that Dr. Cook’s letter provided more information than the form would have elicited. Those in the Quality Department did not share Dr. William’s view. The failure to follow procedure in 2005 probably had little, if any, effect on the outcome for the patients. However, earlier failures to submit occurrence reports related to ER/PR testing probably made a difference.

In April 2003 Dr. Ejeckam stopped ER/PR testing for a period of weeks. The service was re-established on May 2, 2003. Between April 4, 2003, and June 19, 2003, Dr. Ejeckam wrote three memos that addressed certain types of IHC testing, including ER/PR testing. Ms. Elliott, the Director of Quality and Risk Management, Eastern Health, agreed that the subject matter of those memos should have generated an occurrence report. Her opinion was shared by Ms. Predham. Ms. Predham, however, added a rider: it depended on whether this was an expected event within the laboratory.

²⁹ Transcript of testimony, Heather Predham, October 16, 2008, p. 47.

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During the period from March 2003 to June 2003, four cases occurred involving changed ER/PR results upon re-testing of individual patients. No occurrence reports were filed for these cases. In the case of the first patient, on May 6, 2003, the patient was reported to have been negative for ER/PR and a pathology report was signed out (or signed off in Meditech).³⁰ On May 9, 2003, the stains were repeated “due to quality assurance issues.” This time ER was said to be positive in 80% of the cells and PR positive in 10%. A replacement report was completed and a phone call was made to the Cancer Centre to alert the treating physician to the change. In the case of the second patient, the first test, done on March 17, 2003, was reported as ER positive less than 1%, PR 15% positivity. The pathologist’s report noted that there were no controls available. The results were signed out. On May 28, 2003, the test was repeated. This time the results were ER 40% staining, PR 73% positivity. In the case of the third patient, the original test was done on August 29, 2002. ER was recorded as negative and PR was said to be positive in approximately 15% of the cases. This time the test was repeated at the request of an oncologist. The re-test, done June 11, 2003, showed ER faint positivity in approximately 10 to 15% of the cells and PR unequivocally positive in approximately 75% of cells. In the fourth patient case, ER and PR were originally reported as negative. These were re-tested at the request of the patient’s oncologist and on March 26, 2003, reported as ER/PR positive. Thus, within approximately three months, the ER/PR status of four cases changed from negative to positive. No occurrence reports were filed, either by pathologists or oncologists, in respect of these four patients. Had occurrence reports been filed, this, coupled with Dr. Ejeckam’s having shut down ER/PR testing in April 2003, would have likely led to a more extensive investigation at that time.

Ms. Predham agreed that the circumstances of those cases, including the fact that the first reports had been “signed off” before the second test was run, would mean that an occurrence report should have been filed. Had the three occurrence reports been filed within such a short period of time, it is likely that the Quality Department would have investigated these occurrences.

³⁰ When a report is signed out or signed off in the Meditech system, it is available to the treating physician.

Interestingly, Dr. Morris-Larkin, the pathologist who had read the slides on the first case, did not think that the change in results (negative ER to 80% positive) should have caused an occurrence report to have been filed. She said that she just believed it somehow related to the work that Dr. Ejeckam had been doing. In short, she did not see the change as being remarkable. “I mean, we do see these kinds of changes. When we’re looking into a case, we repeat stains, we get deeper sections, we get additional levels, and sometimes that does - that does bring us to a specific conclusion. So I would have seen it within that kind of realm of practice that I was doing.” She conceded, however, that had the time between the original test and the later one been months, then an occurrence report should have been filed. Dr. Morris-Larkin agreed, however, that an occurrence report should be filed where there was “anything that may potentially interfere with patient care.”³¹ She opined that under the current regime it would amount to an internal lab occurrence, which would be reported as part of the internal scheme (the report had already been made to the cancer clinic). Dr. Morris-Larkin has been the site chief at the General Hospital since 2006. She is also the acting co-chair of pathology quality management committee at Eastern Health.

In fact there was in the early days of IHC ER/PR testing a case which would meet the description of an occurrence.

An Early “Index” Case: Christine Purcell

Ms. Christine Purcell was diagnosed with breast cancer in St. John’s in June 1998. She passed away on March 7, 2000. Her husband, Mr. Bryan Purcell, told her story at the public hearings.

On July 20, 1998, an ER/PR test conducted in St. John’s determined Ms. Purcell to be ER positive in 5% of cells and PR negative. This was considered a negative result and Ms. Purcell was advised that she was not a candidate for anti-hormonal therapy. A Progress Note on her chart dated March 15, 1999, states that, “Since she was ER and PR

³¹ Transcript of testimony, Dr. Carolyn Morris-Larkin, October 7, 2008, p. 95.

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negative, we have decided not to start her on any hormonal treatments.”³²

Ms. Purcell’s prognosis was poor; over the course of the next year it was determined that her cancer had spread. A relative, who was a physician in Boston, offered to have Ms. Purcell’s case reviewed there. A Progress Note on her chart dated May 28, 1999, refers to the fact that Ms. Purcell was considering sending her x-rays and pathology report to a physician in Boston and that the Cancer Centre would arrange to have the copies of the films and possibly the slides sent to Boston. Mr. Purcell believed that a tissue sample was sent to the United States so that a new ER/PR test could be carried out there, as opposed to a mere re-reading of the original slides. This re-test determined that Ms. Purcell was ER positive. Mr. Purcell recalled that this information was relayed to Ms. Purcell’s treating oncologist at the Cancer Centre. The ER/PR test was then repeated in St. John’s as well. The result was entered on her chart on July 15, 1999. This was also a positive. It stated she was weakly positive in approximately 50% of invasive tumor for ER and weakly to moderately positive for PR in 10-15% of invasive tumour. As a result, Ms. Purcell was placed on tamoxifen for a brief period of time in the final months of her life.

Despite the uncanny similarity between her case and that of Peggy Deane some six years later, it appears no investigation was carried out into the cause of Ms. Purcell’s discrepant ER/PR test results. Dr. Cook testified that the change in Ms. Purcell’s test results in 1999 should have required further investigation. He would have expected the pathologist involved to have been reported to the clinical chief.³³ While the change in her test results greatly affected Ms. Purcell’s confidence in the health care system at a time when she was gravely ill and dependent on the system, no one offered her any explanation as to how this could have happened. One cannot help but wonder how the ER/PR story may have turned out had such investigation taken place in 1999. Perhaps Ms. Purcell would have been the “Index Case” and the problems would have

³² Exhibit C-0105.

³³ Transcript of testimony, Dr. Donald Cook, July 7, 2008, pp. 209-213.

been detected much earlier. Perhaps there would have been no ER/PR story. As Mr. Purcell put it,

We were also unaware, in 1999, of the extent of these problems. You know, we only had knowledge of our own test. I can tell you that if we had known how extensively the problem existed, we would have pursued it further. Maybe we wouldn't be sitting here today and thousands of people wouldn't be in the state that they're in.³⁴

Mr. Purcell was out of the province in February 2008 when Eastern Health announced that the results of the re-tests were available for the deceased families. When he returned to the province in late March, he called Eastern Health and spoke with Ms. Sharon Smith. Ms. Smith advised that his wife's sample had not been re-tested at Mount Sinai, Eastern Health was not re-testing samples that had provided positive results. Mr. Purcell testified that he challenged this position and asked whether there might be concern about false positives, given the inaccuracies in the testing. It is unclear why the original negative test would not have been part of the review.

Dealing with Adverse Events Historically

Over the years there have, of course, been occurrence reports filed by the laboratory medicine program. However, the incidents that caused occurrence reports to be filed were primarily about the tracking of data. Wrong names, labelling problems and inaccurate MCP numbers were given as examples. Technical problems seemed to be viewed as a natural part of laboratory procedures. They were not seen as incidents requiring the filing of occurrence reports.

If the people in the laboratory did not see the ER/PR matter as an event requiring the filing of an occurrence report, it was not treated as an occurrence within the Quality Department either. It was not that they did not see it as an occurrence, though they debated whether it was one or many, but that they did not seem to be able to determine how to deal with it. This appeared to be because of its size and because of the subject matter. Ms. Predham's normal approach in investigating an occurrence

³⁴ Transcript of testimony, Bryan Purcell, March 24, 2008, p. 24.

involved having the staff go through a step-by-step re-creation of what is done during the test. Here she felt that because the DAKO Autostainer was no longer in the laboratory, any such effort would be of little help. Further, the fact that during the weeks after she was informed about the problem she heard about so many factors that might have contributed to the problem, coupled with the nature of the subject matter, led her to conclude that she did not have the skills required to complete the investigation, and that Eastern Health should go outside the organization for expertise in laboratory medicine and technology.

In a somewhat curious twist, around 2004, as part of a province-wide effort to standardize the nomenclature used for such events, a new guideline was developed for disclosure of “adverse events.” An adverse event was described as:

1. An unexpected and undesired incident directly associated with the care or services provided to the patient; and/or
2. An incident that occurs during the process of providing health care and results in patient injury or death; and/or
3. An adverse outcome for a patient, including an injury or complication. (Patient Safety Dictionary, 2003, p. 39)

This document, in fact, did not officially become part of the applicable policies in St. John’s hospitals until August 1, 2005, when Healthcare no longer existed. Though a new term was introduced for the purpose of disclosure, the language of “occurrence” remained for reporting. It would seem that an adverse event is always an occurrence, but an occurrence is not necessarily an adverse event.

The Present Situation

Currently, the clinical chief and the program director report to a portfolio committee, which in turn reports to a Regional Quality Council on issues related to quality. Prior to 2005, they reported to the Corporate Quality Initiatives Committee. This restructuring of committees appears to be an adjustment to the larger and more diverse nature of the services being provided at Eastern Health rather than because quality considerations required the change.

Since 2005 a number of steps have been taken to improve the quality control and quality assurance procedures within the Eastern Health laboratories and, indeed, in the laboratories of other regional health authorities. By 2007 another committee was being formed at Eastern Health: the Pathology Quality Management Program Committee. Its purpose was stated to include the development, implementation, and co-ordination of quality processes within the pathology services that include pre-analytic, analytic, and post analytic phases. It is clear that the lessons of ER/PR were considered in the development of this committee's purpose and functions. One of the members of the committee is the Program Manager, Safety and Quality Management, Medical Services & Diagnostics. That position, created in 2007, is responsible for the development and co-ordination of a comprehensive quality management program within Medical Services and Diagnostics. The successful candidate was instructed that there would be an initial emphasis on the laboratory medicine program.

The Pathology Quality Management Program Committee has had some success in the development of procedures and protocols. But as Ms. Lynn Wade (who at the time of her testimony was the Program Manager, Safety and Quality Management) noted, it is still a work in progress and discussions continue about the purpose and function of the committee. In fairness to the members of that committee, there was a great deal of work to be done. They were not merely updating and refining prior protocols, as much of their work required that they start from scratch.

In addition, there is now a quality assurance supervisor in the division of anatomical pathology. The creation of these two new positions with a focus on quality is a step forward, and no doubt contributed to the progress that was made in creating procedures and protocols for the clinical laboratory in 2007 and 2008.

At the request of the Commission, Mr. Parks and Mr. Hewlett visited a number of laboratories in Newfoundland and Labrador in September 2008. Both Mr. Parks and Mr. Hewlett visited the St. Clare's and General Hospital laboratories. Their report on the two St. John's laboratories reveals that there has been a marked improvement in

documentation and record keeping, though the process was not then complete. Those sections of the policy and procedures manual that were complete were seen by the reviewers as being equivalent, and in some cases superior, to accredited laboratories in other jurisdictions. The reviewers did note, however, that while knowledge and use of the new policies and procedures were evident at the St. Clare's site, there were bench staff at the General Hospital site who did not seem to be aware of the existence of the new manual.

They did note, however, some basic quality control and quality assurance processes that were not being followed. In particular, they emphasized that the collection of quality control information comes to nothing if quality assurance measures are not making use of this information. As Mr. Parks and Mr. Hewlett put it,

There is evidence of troubleshooting with small isolated corrective actions taking place but an overall QA use of the QC information being produced is not evident. This valuable information is being collected, but needs to be used to take corrective actions throughout the process in order to reduce the occurrence. The QA processing of the QC information, the trouble shooting and the ultimate corrective action need to be assigned to a position in the lab.³⁵

In early October 2008, Mr. Bryan Hewlett visited histology laboratories in Corner Brook, Gander, and St. Anthony. He provided the Commission with a "Process Review" for each laboratory.³⁶ The reviews involved observation, questioning pathologists³⁷ and technologists, and examining of the resulting product from each of the different work areas in the histology laboratory. Mr. Hewlett briefly studied the policies and procedures manual for each laboratory and developed questions for laboratory staff. The following is a synopsis of some findings of Mr. Hewlett's findings at the three laboratories:

³⁵ Exhibit P-3119, p. 6.

³⁶ The reviews occurred in Corner Brook on October 2, 2008; in Gander on October 3, 2008; and in St. Anthony on October 6 and 7, 2008.

³⁷ In St. Anthony the sole pathologist was, unfortunately, not available because of a prior travel commitment.

1. conventional phosphate buffered formalin was not being used;
2. arrangements were not in place to require prompt grossing of larger tissue specimens procured after normal working hours;
3. inadequacies were observed in the tissue processor dehydration sequence;
4. there was a failure to ensure the use of liquid paraffin in the heating holding well during tissue embedding; and
5. the overall quality assurance use of quality control information was not evident.

While the Corner Brook and Gander laboratories showed evidence of occasional intermittent problems with the processing of tissue blocks, the St. Anthony laboratory seemed to have an ongoing problem with the processing of tissue blocks.

Mr. Hewlett concluded in respect of the Gander and Corner Brook histology laboratories that:

I believe that the laboratory's efforts to date, in regard to the handling of fresh breast specimens, fixation policies/procedures and grossing practices, places them in compliance with the important pre-analytic portions of the Canadian Consensus guidelines for HER2/*neu* testing, the ASCO/CAP guidelines for HER2 testing and the soon to be published *ad hoc* committee ER testing guidelines.³⁸

He concluded that the same was not true of the St. Anthony histology laboratory. Mr. Hewlett noted the following in respect of the challenges faced by that facility:

Specimens from Labrador City and Goose Bay are placed in fixative and delivered on an irregular daily schedule depending on availability of transport. This is appropriate for small (<1.0cm thick) specimens but completely unacceptable for larger specimens including breast. The larger specimens need very large containers for fixative and weigh a considerable amount when appropriately packaged for air shipment. Arrangement will have to be made to train appropriate personnel at these locations to slice the larger tissues appropriately, fix them for the correct period of time and then replace the fixative with a smaller amount for shipping. This will invariably prolong

³⁸ Exhibit P-3367; P-3366.

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fixation past the recommended 48 hours in the fixation policy adopted from St. John's. The policy will need to be written to accommodate these lengthened fixation times.³⁹

Some pathologist positions in Newfoundland and Labrador still have not been filled. As of October 7, 2008, Dr. Morris-Larkin stated that there were five vacancies in St. John's hospitals.

In 2005 Eastern Health enrolled in both the College of American Pathologists (CAP) and the National External Quality Assessment Scheme (UKNEQAS) testing proficiency programs.

These two external proficiency programs are well established and many Canadian laboratories use one or both of them. The CAP (College of American Pathologists) program is directed to professional pathology slide interpretation. A laboratory receives from CAP stained slides of unknown specimens for review and interpretation by pathologists. The interpretations are then returned to CAP. CAP plots the results from many different laboratories on a graph and provides the graph to participants who can then compare their performance to that of other pathologists. The UK NEQAS (United Kingdom National External Quality Assessment Service) provides an external proficiency program that is directed to assessing the technical production of stained slides. The NEQAS program involves the staining by a laboratory of slides provided by UK NEQAS. The stained slides are then returned to UK NEQAS. Expert NEQAS assessors provide a detailed report to participating laboratories critiquing the staining methodology and providing advice as to possible improvements that might be pursued.

At Eastern Health, there is now a new reporting procedure for a "sentinel event," which is defined as "an unexpected incident, related to system or process deficiencies, which leads to death or major and enduring loss of function for a recipient of health care services." There is also a new policy on occurrence reporting. Ms. Predham agreed that according to the criteria of today, the ER/PR problem would be a sentinel event.

³⁹ Exhibit P-3368.

A new electronic system for reporting occurrences is under development. This system is designed to improve the reporting of adverse events by making reporting faster, simpler, and more complete. The system will also assist the person completing the form by providing information and asking questions that are relevant to the area of medicine from which the report is coming. It will enable the Quality Department to track adverse events more easily. The electronic system does not, however, change the fundamentals of the policy on reporting. Like the current system, it will be a stand-alone system, not integrated with other patient information. For example, occurrence reports will be separate from clinical records.

In addition to Eastern Health's corporation-wide occurrence report for adverse and sentinel events, there is now an internal laboratory procedure for documenting all issues regarding quality of IHC staining and all corrective actions undertaken. Forms for recording quality issues, or what Dr. Morris-Larkin described as internal lab occurrence reports, are to be filed in the correction action logbook whenever a problem is noted and resolved within the laboratory. These were to be dealt with within the laboratory medicine program. If a report left the laboratory and there were an adverse event or "a near miss," then the corporation-wide system for reporting of occurrences would operate. There is also a Pathology Error Disclosure policy, which came into effect on September 15, 2008. While the general procedure is consistent with the occurrence procedure in respect of reporting, this policy has a detailed process for resolving differences of opinion regarding diagnosis.

The mandate of the Quality Management Program Committee for Anatomical Pathology has been determined. The review of data being collected is ongoing. When necessary, because of the nature of the data being audited, other people may assist the committee for the purpose of the completion of the review.

In summary, since 2005 much work has been done in the development of policies and procedures for IHC. This work must be completed. It is important that policies not remain stagnant. While Eastern Health's current policies, for example, in some cases include revision dates, these must be included for all policies, and a process must

be in place to ensure all policies are regularly reviewed and updated if necessary. Most important, however, is that the policies actually be followed and that when the reporting is done the quality assurance activities follow. Ms. Predham was very specific that over the years the Quality Department had done a lot of staff education on patient safety, occurrence reporting, system error and individual error. However, she too cited the literature regarding underreporting of occurrences. This highlights the necessity of vigilance by all involved to ensure policies and procedures are followed. Policies and procedures relevant to patient safety are of no value if they are ignored.

Chapter Nine

The Oncologists' Role in the ER/PR Problem

The Oncologists' Role in the ER/PR Problem

The ER/PR problem was essentially a clinical laboratory problem. Some oncologists, with justification, saw themselves as having to deal with the fallout from problems that they did not create. Oncologists often had to deal face to face with patients angry at Eastern Health or the health system generally.

As already discussed, two of the oncologists, Dr. Kara Laing and Dr. Joy McCarthy, were instrumental in pushing the initial investigation of the issue. Further, the discovery of the problem in 2005 can be traced to connecting Peggy Deane's cancer (invasive lobular) to information that statistically it should very likely be ER positive.

In the summer of 2005, it was generally believed within Eastern Health that Dr. Laing had received information that all infiltrating lobular carcinomas should be ER positive. Dr. Robert Williams recalled that Dr. Donald Cook told him that in a conversation on May 17. In notes of their meetings on July 14, Dr. Williams and Dr. Cook each recorded that at Sloan-Kettering the incidence of positivity of lobular invasive carcinoma had gone from 75% to 100%. The note by Dr. Williams concerned the discussions at a meeting of the Group held at 5:00 p.m. The reference to the positivity rate is included with a number of bullets attributed to Dr. Laing and follows a bullet which states: "New information - Lobular CAs should all be ER/PR positive."¹ It is not clear whether Dr. Cook's note was made at the meeting of the Group or a meeting of the Core Group held on the same day. Dr. Cook added: "get article from Kara Laing." No one at Eastern Health was able to find any published article that supported this idea.

Dr. Laing testified that her only communications with Dr. Clifford Hudis of Sloan-Kettering during the spring and summer of 2005 were the emails in April 2005, when she consulted him on the Peggy Deane case. There was no reference in their email exchanges to any such study

¹ Exhibit P-0505.

having been done at Sloan-Kettering. Dr. Hudis merely noted that ER negative was very rare for infiltrating lobular and that he had never seen an infiltrating lobular carcinoma with negative ER results. Dr. Laing's recollection was that in the fall of 2005 she met Dr. Hudis at a medical conference and it was on that occasion that he had stated that on a review of lobular carcinomas in Sloan-Kettering's tumour bank, 100% were ER positive. She stated that at no point did she say anything about a conversion rate, not from 75% to 100%, nor from 95% to 100%. Dr. Laing suggested that perhaps Dr. Williams had misunderstood her. She had said that 75% of all breast cancers were ER positive and that Dr. Hudis had never seen a negative infiltrating lobular case. Dr. Williams, she felt, must have mistakenly linked the two statements.

If that is the case, Dr. Cook, a pathologist, made a similar error. Whatever Dr. Laing said during the meetings in the early summer of 2005, a number of those who heard her believed that there had been a study on the subject of positivity rates for lobular carcinoma conducted at Sloan-Kettering.

I am satisfied that Dr. Laing did refer to there having been a recent study in support of that position. During her testimony Dr. Laing was asked about a number of cases which, to protect patient privacy, were referred to only by number. In one of those cases (patient number 2), Dr. Laing had requested, on May 6, 2005, a repeat ER/PR test. On the form requesting a repeat ER/PR test, she had written: "Please re-do ER/PR on [specimen number] as was reported as negative & it was a lobular CA which is very unusual as recent studies suggest all lobular are +ve."

One of the questions that must be asked is whether an oncologist who receives an ER negative test result for a patient with a diagnosis of invasive lobular carcinoma should question the result. A number of the oncologists were asked what they had learned in their training regarding the percentage of lobular or invasive lobular breast cancer which should be positive. In part, of course, the response depended upon when and where they were trained. Dr. McCarthy, who did her oncology training at the University of Toronto between 1999 and 2001, recalled she had been taught that lobular cancer would be likely to be somewhere in the range

of 85% positive. She did not recall any occasion, prior to Ms. Deane's case, when she had requested a repeat of an ER/PR test. As to Ms. Deane's case, Dr. McCarthy said that, until the email to Dr. Laing from Dr. Hudis, she believed that the percentage of ER positive lobular cancers would be 85%, and as Ms. Deane's was a poorly differentiated lobular cancer, she did not question it. Dr. Laing gave similar evidence. Dr. Laing began practice as a medical oncologist in St. John's in 1999, after completion of training in medical oncology at the University of British Columbia and the British Columbia Cancer Agency, and a research year with the National Cancer Institute of Canada. Her recollection was that during her training she learned the percentage of lobular carcinomas that would be hormone receptor positive was somewhere around 85-90%. It must be noted, however, that after the Deane case the oncologists were able to identify a number of other patients with invasive lobular carcinoma and a negative ER status on initial testing, but who were reported as positive ER on re-test.

In his report, Dr. Banerjee opined that 92% of invasive lobular carcinomas are ER positive.² Dr. Banerjee cited a journal article³ as authority for that proposition. In his testimony he added, "in general practice it's almost virtually 100%." In testimony before the Commission, he confirmed that in 2002 and earlier, it was known that invasive lobular carcinomas should be ER positive. He further opined that both oncologists and pathologists should have been aware of this. Consequently, it was the opinion of Dr. Banerjee that Ms. Deane's results should have been questioned by both pathologists and oncologists in 2002. Other experts in pathology made similar statements about the expectation of hormonal receptor positivity for invasive lobular carcinomas. Dr. Brendan Mullen stated that with a lobular carcinoma he would expect a positive result on hormonal receptor testing more than 90% of the time. As a result, if he found a negative ER result, even though technically the slide looked fine, he would repeat the test before reporting on it. Dr. Frances O'Malley, a breast pathologist at Mount Sinai Hospital, also stated that she would re-test if an invasive lobular was

² With this information, efforts to find a publication reporting on a Sloan-Kettering Study were abandoned.

³ *J Clinical Oncology* 2005 Jan 1; 23(1): 41-8.

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negative because a negative invasive lobular is so rare. She could remember having seen only one negative invasive lobular. She estimated 90-95% of such cases would be positive and she had had that knowledge since before 1998. Dr. David Dabbs stated that he had learned during his residency in the early 1980s that virtually all lobular carcinomas are positive.⁴

⁴ Transcript of testimony, Dr. David Dabbs, September 15, 2008, p. 226.

Chapter Ten

Communications Part I: The Chronology

Communications Part I: The Chronology

Terms (c) and (d)¹ of the Terms of Reference of this of this Inquiry are directed to communications. Primarily, the communications under consideration are between Eastern Health and the affected patients or their families, the public, and other regional health authorities. One must not lose sight, however, of the fact that other regional health authorities and the Government of Newfoundland and Labrador are “responsible authorities” under the Terms of Reference. This dictates that their communications with patients, their families, and the public must also be examined.

As the story of communications unfolds there will be references to internal communications difficulties within organizations. Though internal communications are not the subject of a specific Term of Reference, they are important to the actions taken by organizations. For example, as will be seen, even those directly involved with the ER/PR issue within Eastern Health did not always have the same understanding of decisions made and the terminology used, and this affected what was said to others.

In addition to making decisions about the investigation of the ER/PR problem, the Group made many of the decisions regarding communications with patients or their families, the public, and in some cases other regional health authorities. When it came to decisions about when and how to communicate with others, the pathologists and technologists within the Group took a lesser role, while the oncologists and communications specialists became more influential. However, the

¹ (c) inquire into whether, once detected, the responsible authorities responded and communicated in a timely manner to those women and men who needed re-tests and those who were being tested for the first time;

(d) inquire into whether, once detected, the responsible authorities communicated in an appropriate and timely manner with the general public and internally within the health system about the issues and circumstances surrounding the change in test results and the new testing procedures.

pathologists and technologists continued to influence the description of the problem and, therefore, what was being communicated to others.

May - July 2005

In his letter of May 24, 2005, to Dr. Robert Williams, Dr. Donald Cook wrote: “if it is identified that we have a much more significant conversion factor problem involving many patients, we would need to seek advice and guidance from QI [the Quality Department] on how best to disclose this information, as this involved breast cancer patients across the province.” This is the first recorded reference to what was to become the major issue of whether, when, and how to disclose to patients. The letter of May 24, 2005, reflects, I believe, the concerns raised in the earlier conversation between Dr. Williams and Dr. Cook. Dr. Williams wrote on his copy of the May 24 letter: “copy Heather Predham, set up meeting with Dr. Cook, Ms. Predham and myself.” Ms. Heather Predham recalled that Dr. Williams spoke to her about the ER/PR issue around the 10th of June. She remembers her first meeting on the subject as having taken place on June 12. The Core Group was formed. At that stage their energies were primarily directed to determining the nature and size of the problem. It was a proper first step.

Dr. Williams, Dr. Cook, and Terry Gulliver met frequently after May 17. Dr. Williams’ notes of July 8, 2005, reveal that by that date he had concluded that the problem was not an anomaly confined to a limited period. He would have known that the problem was likely a large one.² In those same notes Dr. Williams recorded that he had advised the CEO, Mr. George Tilley, about the existence of the problem.³ Dr. Williams raised with Mr. Tilley the possibility that they would have to do some type of public disclosure rather than speaking individually with each patient. Dr. Williams asserts that his position always was that there should be disclosure of the problem as quickly as possible, and that in the circumstances public disclosure was the only realistic option. It

² By June 29, 2005, Dr. Carter had advised Dr. McCarthy of the results of the first group she re-tested. Also she was well underway in the review of the second group. If those numbers reflected the results from 1997 to 2004, there was a large problem.

³ Mr. Tilley’s notes indicate that he was informed of the problem by Dr. Williams on July 7, 2005.

was not until mid-July that Mr. Gulliver began to identify all patients who had had ER/PR testing for the purpose of Dr. Beverley Carter's work. No one was looking for the information that would be necessary to contact patients by letter or phone.

As noted elsewhere, there were no minutes kept of the meetings of the Group and therefore it is difficult to determine how and when certain decisions were made. It is clear that for a period in July 2005, Eastern Health was preparing for a public disclosure of the ER/PR problem. Dr. Williams' notes of July 12, 2005, indicate the concerns at that time. Among the points listed were:

1. Test all samples of living patients.
2. What are our positive rates for infiltrating lobular and ductile (sic) cancer.
3. Look at our rate of positivity by year
4. ...
5. Set up process to inform Oncologist in the Cancer Care Program.
6. ...⁴

Other decisions on that date related to the investigation of the cause of the problem and the implementation of recommendations in the letter of Dr. Cook written on May 24, 2005.

However, at a meeting of the Core Group on July 14, 2005, the discussion was directed to identifying those who had ER and PR receptor testing and rechecking them using the Ventana. Dr. Williams also noted "Advise the public." In an email of July 15, 2005, from Ms. Deborah Thomas-Pennell to Ms. Susan Bonnell, Ms. Pennell reported on information provided to her by Ms. Predham. Ms. Nancy Parsons, then a patient relations officer with the Quality Department, was considering how to implement a hotline and they were thinking they "may want to release mid-late next week." At that point, Eastern Health was preparing for a public announcement and the setting up of a hotline to enable patients to contact Eastern Health if they had questions.

⁴ Exhibit P-0501.

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There was another meeting on July 14, of Dr. Williams and a number of physicians, including surgeons and oncologists. Dr. Williams' notes of that meeting do not mention communications with patients.

On July 18, Ms. Predham drafted an update intended for Mr. Tilley. Ms. Predham distributed a draft of the update for Mr. Tilley to others in the Core Group. In her email she noted that she had not included any information regarding Dr. Gershon Ejeckam's memos in 2003 and asked: "should we?" Ms. Predham explained that she was not intending to suggest that Mr. Tilley not be told about the Ejeckam memos but merely asking if it was appropriate to attach the memos to this document. A few days later, when a briefing note was prepared for the Minister of Health and Community Services, Mr. John Ottenheimer, there was reference to Dr. Ejeckam's actions in 2003. As Mr. Tilley led the group that met with the Minister on July 21, 2005, he had to be aware by that date that Dr. Ejeckam had done something in 2003. However, Mr. Tilley did not recall seeing Dr. Ejeckam's memos and for that reason the level of his understanding at that point of what Dr. Ejeckam had done and said is unclear.

The update, which was eventually sent to Mr. Tilley under Dr. Williams' signature, includes the following:

The public will have to be informed. Corporate Communications have been involved and, as at least five patients are aware of this information already,⁵ disclosure has to be made quickly. After meeting with the surgeons and oncologists it was decided to wait until we were able to get more information regarding retesting, the anticipated timelines and a support line established. This support line for patients will be coordinated through QSI [Quality Department]. Legal counsel will review the proposed media release before it is distributed.⁶

This appears to be the first suggestion that there should be a delay in revealing the problem. I understand this caution, however, to be not about the method of communication but about the content of the public

⁵ In fact, by then more than five patients had been informed of changed ER/PR status following re-testing.

⁶ Exhibit P-1930.

communication, the need to have more information than was available at that time and the need to establish a hotline before advising the public. Of course, at that point the re-testing was being done in-house by Dr. Carter.

July 18, 2005, was an important day in the ER/PR story. Early in the morning Ms. Predham was communicating with others in the Core Group, asking their views on inclusion of information regarding the Ejeckam memos in the memo for Mr. Tilley. At 12:04 p.m. she sent the draft on to Ms. Pennell in Strategic Communications.⁷ By 12:29 p.m. she had incorporated the changes suggested by Dr. Cook and Mr. Gulliver, and was sending the update to Dr. Williams. Dr. Cook and Mr. Gulliver had agreed that Dr. Williams should be the one to sign it. In the email accompanying the final version of the update, Ms. Predham adds:

I was speaking to Deborah Thomas today and the Department of Health has been notified and is now involved. They would like a letter sent to each woman outlining the problem and the steps we are taking to address it. That draft letter will have to be seen by our lawyer first of course.

I guess we will have to decide tomorrow or the next day re: advising the public?⁸

Ms. Predham was clearly cautious about communicating directly with patients or with the public without first having HIROC's solicitors examine the letter or media release. She wanted to make sure that Eastern Health did not say anything that would interfere with any defence available to it in potential litigation.

Strategic Communications was meanwhile preparing for a public release. Drafts of briefing notes, media releases, and a letter to patients were prepared. The letter was to advise patients that re-testing would be done and explained the reason for the re-testing as follows:

⁷ This Division reported to the Vice President, People and Information Services.

⁸ Exhibit P-0300.

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Due to improved technology and the finding of some earlier, inconsistent results, Eastern Health has begun retesting a select group of breast cancer patient samples to check for estrogen and progesterone receptors.

The draft letter also states that if treatment change is required the patient will be contacted by his or her family doctor or oncologist. It adds: "if you are not contacted, your result did not change." The draft letter to the patients was sent on July 18, 2005, to Ms. Parsons. Ms. Predham replied to Ms. Pennell, making some suggestions for changing the wording and raising certain questions. Primarily, Ms. Predham raised questions about the use of the letter: they had not yet determined how patients were to be notified of results; whether they could link with others, like the Cancer Society, and send out a joint message; and how they were to deal with notification of the patients from Saint-Pierre. Ms. Predham did not question the premise that a letter should be sent to patients.

In the meantime, as the comment attributed to Ms. Pennell indicated, contact was being made with the Department of Health and Community Services, though neither Ms. Predham nor Ms. Pennell could say who had made the contact or when. The Commission heard about two contacts between Eastern Health and the Government on July 18, 2005. The CEO of Eastern Health, Mr. Tilley, called Mr. John Abbott, Deputy Minister of Health and Community Services. Mr. Abbott recalled that it was a brief conversation. The information was sufficient, however, for Mr. Abbott to conclude that there was a major issue involving breast cancer and if, as he had been told, there was a need to go public soon, then the Minister would have to be briefed. Mr. Abbott could not recall whether he spoke to the Minister on the 18th or the 19th, but he advised him that Mr. Tilley was coming to brief him on a significant issue.

On that same day, July 18, 2005, Ms. Carolyn Chaplin, Director of Communications for the Department of Health and Community Services, received a call from Eastern Health. Ms. Chaplin recalled that it was Ms. Bonnell who had made the call. Ms. Bonnell said she had not but perhaps it had been Ms. Pennell. Ms. Pennell is clear that she did not call Ms. Chaplin on the 18th. Late in the day, Ms. Chaplin told Mr. Darrell Hynes, Executive Assistant to the Minister, that she had been advised there was a potentially large problem at Eastern Health. I find that the

Minister, Mr. John Ottenheimer, was not advised until early the next morning, when Mr. Hynes and Ms. Chaplin spoke to him about it.

Mr. Abbott is clear that he did not express any position to Mr. Tilley regarding the sending of a letter to each patient. He did not think any such message would have come from the Department at that stage, as the issue was so new. Ms. Chaplin believed her call from Ms. Bonnell was in the afternoon, in which case Ms. Chaplin could not have been the source of the suggestion that a letter be prepared. Whoever the source, the Minister's position turned out to be consistent with the information provided by Ms. Pennell, as the Minister's position was that letters should be sent to patients.

On the evening of the same day, July 18, Ms. Predham spoke to two representatives of HIROC: Ms. Eleanor Morton and Mr. Michael Boyce. It appears that they called her. The next morning Ms. Predham emailed other members of the Core Group, as well as Ms. Bonnell and Ms. Pennell. The email was copied to Ms. Pat Pilgrim. Ms. Predham's email said:

I had a long conversation with representatives from HIROC yesterday evening.

As a bit of background, they are currently defending a class action lawsuit against Health Labrador re: the reprocessing of equipment. Apparently the aspect of this lawsuit on which they are most vulnerable was the method the people were informed. Ches Crosbie has [alleged] in the lawsuit that the people suffered significant mental anguish from the way they were told and that the risk of disease from their exposure did not warrant the stress and anxiety they suffered by being told.

The organization felt the need to disclose publicly, ran it by their legal counsel and then wrote letters to every person affected and sent out a news release (sound familiar??). Their vulnerability comes from the lack of weighing out the risk from the exposure versus the anxiety of being told about it. In this case the risk from the exposure was very small.

This leads us to our situation. It's not that they don't want us to disclose, they just don't want us to disclose until we are sure of our facts. I've had a quick voice mail from Dan [Boone] after my chat with HIROC, they contacted him after they hung up from me, reiterating this and that they will be in touch again in the morning.

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So, I guess we will have to reevaluate where we are before we plan to send those letters etc?

Should we chat about this face to face?⁹

In her testimony Ms. Predham explained that “until we are sure of our facts” referred to statements about the cause of the problem. She added an illustration: “if we were going out and saying that -- this is improved technology, he wanted to make sure that that’s what we were talking about.” Her interpretation of her discussion on July 18, 2005, with Mr. Boyce and Ms. Morton of HIROC was that in the Labrador class action¹⁰ the health authority had responded too quickly, before it fully understood the situation. Mr. Daniel Boone, the solicitor for HIROC, had a different view of “being sure of the facts”:

I would have presumed that the facts about which they needed to be sure were whether or not they had a problem which could affect a broad group of patients. I mean, that would seem to me to be a fact that would be necessary to know before you disclose to those people.¹¹

On July 19 at 1:57 p.m., Mr. Abbott emailed Mr. Tilley (with a copy to Ms. Chaplin) to advise him that he and the appropriate staff of Eastern Health were to brief the Minister on Thursday the 21st at 9 a.m. Mr. Abbott requested that a briefing note be forwarded to him by Wednesday. In a separate email, Ms. Chaplin advised Ms. Pennell that the briefing materials to be prepared for the Minister “will not go beyond the department for now.”¹² On the 20th, Mr. Abbott and Mr. Tilley were advised by Ms. Pennell that the latest information would not be known until after a meeting to be held at 4 p.m. that day.

⁹ Exhibit P-0073.

¹⁰ The term class action will be used to describe an action taken by patients against Eastern Health whether it was before or after the application for certification of a class action. The Labrador class action was *Rideout v. Health Labrador Corp.* 2007 NLTD 150, 270 Nfld & P.E.I.R.90.

¹¹ Transcript of testimony, Daniel Boone, October 29, 2008, p. 224.

¹² Exhibit P-0134.

On the 19th around midday there was a meeting of the Core group, as well as Ms. Bonnell, Ms Pennell, and Mr. Boone. Ms. Predham felt that the meeting of the 19th did not change the plan then existing that Eastern Health send letters to the patients informing them that there was going to be re-testing. In addition, there would be a public statement. During the meeting, Mr. Boone was asked about the Labrador class action. Mr. Boone recalled that his response was that the Labrador class action was not unique and that there were cases in which the cause of action was based on either the decision to notify patients or the method of notification. Mr. Boone talked about notification before having done due diligence to determine whether or not there is a problem. He believed that much of the information presented at the meeting was for his benefit, as others in the room would have already been aware of the information being presented. Among the points made by Mr. Gulliver was an assertion that he and the technologists were certain they were doing the test correctly and following instructions and, furthermore, that controls had been run.

At that meeting Mr. Gulliver also announced that his preliminary calculations suggested positivity rates within Eastern Health were within the norm. Mr. Gulliver was to have the final figures within a few days. Mr. Boone believed there was a consensus that it was best to await the statistics from Mr. Gulliver. Mr. Boone recalled that Dr. Williams, at the end of the meeting, had asked if he was comfortable with the decision to wait until Mr. Gulliver's figures were available before making any further decisions on the course of action to be taken. Dr. Williams understood Mr. Boone and HIROC wanted Eastern Health to make sure they had enough information or good information before sending letters to patients. Later that day Dr. Williams and Mr. Tilley had a discussion. Mr. Tilley's notes of that communication include:

Legal counsel cautions release pending full results
Agreed to delay release
New technology is 10 X more sensitive¹³

¹³ Exhibit P-0329.

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The reference to “full results” does not appear in any of the notes of the July 19 meeting, nor in the recollections of the witnesses who attended the meeting. However, as will be discussed later, in Dr. Williams’ communications with Dr. Larry Alteen, Vice-President of Medical Services for the Central West Health Care Board, on October 7, 2005, Dr. Alteen recorded Dr. Williams as having said that HIROC did not want to disclose to patients until the results were back. Since in July the investigation of the problem was internal, full results can only refer to the full results of the then planned re-testing of all ER negative cases by Dr. Carter. Mr. Tilley’s notes also indicate that Ms. Bonnell told him about what had transpired during the meeting:

Today’s meeting revealed the potential that scope of problem restricted on basis of review of percent of positivity results for 2003 being 75% which is consistent with national benchmarks.¹⁴

It was not until the middle of August that Eastern Health had a list of names of the affected patients to be contacted.

The next day, July 20, the questions raised by HIROC and Mr. Boone were clearly still on the minds of those at Eastern Health. Ms. Predham’s notes of that day are difficult to decipher. They include:

If there is a problem with what we did by making an exposure will we create a
- can’t expect HIROC to pay for it.¹⁵

Ms. Predham’s explanation of that note was: “If we went out and said that the problem was due to improved technology when it wasn’t, then we would create an exposure that didn’t really exist. The exposure already existed because we were going to re-test all these patients and we were going to find people that converted and we already had an issue because we didn’t respond in 2003 like we were in 2005.” Regarding the reference to HIROC not paying for it Ms. Predham said: “I guess that was – that’s an understanding that we always had. If we – and that’s why we always reiterated with – that’s why we always sent information to our lawyers, to make sure that we weren’t inadvertently undermining our

¹⁴ Exhibit P-0329.

¹⁵ Exhibit P-2940.

insurance policy.” It is clear that regardless of the message HIROC officials intended to deliver, they caused Eastern Health to re-evaluate their plans. It is also clear that Ms. Predham, Mr. Boone, and Dr. Williams each took something different from the discussion on July 18 and 19, at least according to what was explained to the Inquiry.

While on July 19 Eastern Health was busy with internal meetings on the ER/PR issue, within Government the news of the issue was traveling outside of the Department of Health and Community Services. On the morning of July 19, 2005, Mr. Gary Cake, then Assistant Secretary to Cabinet for Economic Policy, Cabinet Secretariat, emailed Mr. Robert Thompson, then Clerk of the Executive Council and Secretary to Cabinet:

Carolyn Chaplin just called from HCS [Department of Health and Community Services] to provide a heads up that a major story will break from the Eastern Health Board as early as this Thursday, but more likely next Monday.

The Eastern Health Board has recently discovered errors in its breast cancer testing program. This matter affects clients who were subject to breast cancer testing from 1997 to April 2004. I understand that an estimated 1200 to 1500 clients will need to be retested. The Eastern Health Board is currently working on a strategy for communicating this news to affected clients and the public at large. Legal advice is being engaged in this process.

HCS will be advised of the communications strategy.

A briefing note is currently being prepared.

Carolyn has also alerted Elizabeth [Matthews] to this matter.¹⁶

This appears to have been the first notification of the ER/PR problem to anyone in Government outside of the Department of Health and Community Services. Mr. Thompson promptly forwarded Mr. Cake’s email to Mr. Brian Crawley, with the notation that “This is major. Once the solution is set into motion, we will expect the Department and the Board to undertake appropriate evaluation to determine why this happened.” Mr. Thompson also replied to Mr. Cake, saying:

¹⁶ Exhibit P-0312, p. 3.

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Please ensure the Department and the Board include in their com plan the assurance that once the solution is set into motion, that an evaluation will be done to determine the specific or systemic reasons why this occurred so that the matter will be properly addressed in the long term. I'd like to see this aspect before it goes out.¹⁷

Ms. Elizabeth Matthews and Mr. Crawley worked in the office of the Premier of Newfoundland and Labrador. Ms. Matthews is the Director of Communications and Mr. Crawley the Chief of Staff.

At 2:37 p.m. on July 19, Ms. Chaplin emailed Mr. Gary Cake and copied Mr. Abbott:

Further to this morning and incoming information this afternoon, no action is required at this time. We have arranged a briefing with the health authority for the latter part of this week and will be in a better position to forward relevant briefing materials at that time. No public announcement will be forthcoming this week and there is a possibility that the significance of any announcement will be minimized.

Mr. Cake promptly forwarded the message to Mr. Robert Thompson.

Premier Danny Williams' calendar reveals that on July 19, 2005, he attended a swearing-in ceremony for a Member of the House of Assembly, held at Government House. There were no other events in his calendar for that day. Mr. Williams was unable to recall whether he was in the office on the 19th, but he hastened to add that he would have been available to his office staff had they wished to contact him. He agreed that the information provided to his office by Ms. Chaplin early in the morning was of a character that would normally result in his being advised. He further stated that had he been advised before the email of 2:51 p.m., that email would have been characterized as a "stand down" email. That is, the message was the circumstances had changed and no action was required.

Neither Mr. Williams' staff nor the Premier himself could be specific about whether the content of Ms. Chaplin's messages had been passed to him. If he had been advised, I agree that the 2:51 p.m. email is

¹⁷ Exhibit P-0312, p. 3.

properly characterized as a message that no action need be taken by Cabinet Secretariat, and by implication, the Premier’s Office.

On receipt of the second email, Cabinet Secretariat would understand that the Department would be in a better position to provide information after the meeting which was to take place that week. The implication of the message is that Cabinet Secretariat would be given further information, within the week. It would have been reasonable for officials of Cabinet Secretariat to await more complete information. However, both the Department and Cabinet Secretariat can properly be criticized: the Department for not having provided further information to Cabinet Secretariat, and Cabinet Secretariat for not pursuing the matter with the Department when that information did not arrive.

Coincidentally, there was a meeting between Mr. Tilley and Mr. Ottenheimer at 12:30 p.m. scheduled for July 19. Mr. Tilley thought that it was a telephone conversation. Mr. Ottenheimer believed it was a meeting. In any case, both agree it included discussion of the ER/PR problem. Mr. Tilley’s notes of the day include “the sooner the better.” Mr. Ottenheimer stated that he would have told Mr. Tilley that it was best to get the matter made public as soon as possible.

The briefing note that was prepared by Eastern Health in preparation for the meeting with the Minister on July 21 included the following information:

Eastern Health’s Comments	Commissioner’s Comments
1. It dates the discovery of the problem to Dr. Joy McCarthy’s request for re-testing of a patient on May 11, 2005.	Rather than Peggy Deane’s case in April, 2005
2. It notes that the DAKO Autostainer required manual boiling of tissue and measuring of minute mixtures of	It is true that Eastern Health mixed many of their own solutions used in ER/PR testing; that was a matter of choice. Pre-diluted reagents

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Eastern Health's Comments	Commissioner's Comments
immunoperoxidase staining.	were available for use with the DAKO Autostainer.
<p>3. It states that the Ventana Benchmark automates the full process and all reagents are pre-mixed by the company.</p>	<p>As to the use of the pre-diluted reagents with the Ventana Benchmarks, this is because Eastern Health chose to purchase the pre-diluted reagents rather than dilute them or use some other manufacturer's product.</p>
<p>4. It adds the following regarding activity on July 18 and 20.</p> <p>Considering the 50-85 per cent acceptable range in standard text books and Mount Sinai's standard of around 70-80 percent, this also reconfirms that our numbers are legitimate. Regardless, the laboratory is still going ahead with retesting the specimens and officials will meet with the oncologists to see how they would like to proceed with informing patients of their conversion and possible change in treatment.</p>	
<p>July 18, 2005: Laboratory managers in St. John's began reviewing the statistical data for 2000-2004 to see if there were any inconsistencies in the findings of positive conversions or if this could just be a matter of the sensitivity of the Ventana system.</p>	<p>I have no explanation for the activity on July 18, 2005. Mr. Gulliver was examining positivity rates on the 18th. He reported more widely on the subject on July 20. I assume that the reference to positive conversions on the July 18 is an error. I shall return to the use of positivity rates by Eastern Health later in the report.</p>

Eastern Health’s Comments	Commissioner’s Comments
<p>July 20, 2005: Upon review of the statistical data [it] has been concluded that the positivity rates are, while on the low end of the scale, within acceptable range. Total positivity numbers for 2000 are 62 percent; 2001 - 77 per cent; 2002 - 68 per cent; 2003 - 83 per cent and 2004/05 (after a full year with the Ventana system) - 90 per cent.¹⁸</p>	

Other information provided in the briefing note was:

1. It explains the benefits of hormone therapy for some patients and that anti-estrogen therapy may benefit patients who are ER negative but PR positive.
2. It states that the literature suggests about 50-85% of breast cancers are ER positive.
3. It explains how the decision was made to do the re-testing on the Ventana Benchmark, gives the results from the first 25 re-tested by Dr. Carter and notes that on July 14, 2005, the decision was made to expand the re-testing to all patients who were ER/PR negative from 1997 to 2004 and the steps taken by Dr. Cook to advise other laboratories in the province.

The “Actions” section of the July 20 briefing note outlined a number of the planned activities. Those activities included that Dr. Williams had asked that an investigation be conducted into the five-week stoppage of immunoperoxidase staining for ER/PR receptors in 2003 by Dr. Ejeckam, and that Dr. Williams had asked if they could “repeat any of the negative tested specimens again on the ‘old’ DAKO system to confirm that it was indeed the system and not a laboratory error. Terry Gulliver, HCCSJ Laboratory Program Director says it is unlikely we

¹⁸ Exhibit P-0075, pp. 2-3.

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would be able to obtain such a system at this time to re-test on that method.”¹⁹ Of course, DAKO Autostainers were in use in many institutions across the country, including Mount Sinai.

In this briefing note it is difficult to see how Eastern Health could maintain that at that point it was suggesting that the errors were attributable to anything other than the DAKO Autostainer. There is a distinction being made between laboratory error and the old DAKO system that can only lead to the conclusion that the term “system” in that briefing note referred to the operation of the machinery. The briefing note does not refer to any preparations that had already been made to tell patients or the public. It does say:

Considering the 50-85 per cent acceptable range in standard text books and Mount Sinai’s standard of around 70-80 percent, this also reconfirms that our numbers are legitimate. Regardless, the laboratory is still going ahead with retesting the specimens and officials will meet with the oncologists to see how they would like to proceed with informing patients of their conversion and possible change in treatment.²⁰

On July 20, 2005, the day before the meeting with the Minister, Mr. Tilley emailed Ms. Joan Dawe, the chair of the Board of Trustees of Eastern Health, to advise her of the problem. This was the first communication with the Board of Trustees on the subject. Mr. Tilley said the following:

I have been [in] touch with the Minister who is edging us to go public asap. No doubt about the need to do that, but not until I know the size and shape of it. For example, late yesterday the size of the issue began to shrink as managers compared the results of these tests with national benchmark outcomes and found that in 2003 we were consistent. I am expecting a briefing later this morning when the results of this comparison are made for other years.²¹

When Mr. Tilley stated that the issue had begun to shrink, he was obviously referring to the positivity rates that were being prepared by Mr. Gulliver. The assumption appears to be that if positivity rates were

¹⁹ Exhibit P-0075.

²⁰ Exhibit P-0075, p. 3.

²¹ Exhibit P-0074.

within a range as wide as 50-85 percent, that would somehow demonstrate the validity of Eastern Health's ER/PR test results.

Mr. Ottenheimer recalled that at the meeting of July 21, Eastern Health was saying they would notify patients on receiving the re-testing results, as opposed to notifying them prior to re-testing, and that Eastern Health preferred not to go public. Mr. Ottenheimer recalled that Eastern Health said this plan was supported by the oncologists. I think it likely that the Minister has confused the meeting of July 21, 2005, with one in August. The only involvement of the oncologists on the issue of communications up to that point had not suggested that they were arguing for waiting until the return of the re-testing results to inform patients, though as noted earlier Dr. Williams seemed to understand that to be the advice of HIROC.

Both Dr. Williams and Mr. Abbott, who attended the meeting with the Minister, recalled that at its conclusion the notification of patients, and perhaps the public, would go forward but that Eastern Health did not feel ready to begin notification at that point. Mr. Hynes summarized the meeting as follows:

My understanding was Eastern Health were going to go back and meet with their oncologist the following week, ... to bring them on board to discuss, I guess, in a more systematic way how we would go about or how Eastern Health, sorry, would go about notifying individual patients and what the doctors' preference would be, whether that would be, you know, letters, registered letters, individual phone calls. I mean, you know, whatever that process would be. They wanted to get the oncologists to the table so to speak.²²

Eastern Health was to get back to the Minister about where they were going with the issue and make sure he was kept informed. Mr. Hynes recalled Mr. Tilley telling the Minister that they did not have any idea at that point what they were dealing with. Mr. Hynes impressed me as a witness who was direct and precise. When he was doubtful about when something was said, he said so. His recollection of events was, however, quite good. Based on Mr. Hynes' recollections, I am satisfied that the subject of the Labrador class action suit was raised at the meeting

²² Transcript of testimony, Darrell Hynes, June 18, 2008, pp. 244-245.

with the Minister on July 21, 2005, in the context of a discussion about disclosure and what form of communication would be preferable. Mr. Hynes confirmed that the Minister's preference was to send out individual patient notifications as quickly as possible, and that these would be followed by public disclosure. However, the Department was never given any draft patient letters and Mr. Hynes did not remember ever receiving any explanation as to why the patient letters had not gone out or being told that there were to be no letters.

Ms. Chaplin's notes of the July 21 meeting add a point about "Positioning: Option for retesting. New tech avail. etc. instead of 'errors in testing.'"²³ Ms. Chaplin stated that these were not recordings of her own thoughts but rather what she was hearing from Eastern Health during the meeting, though she could not be precise about who said it. Ms. Chaplin expressed the opinion that the draft press releases then being considered by Eastern Health demonstrate that they were considering telling patients that the re-testing was being done because of the availability of new technology rather than because of concern about errors in prior testing. I agree with Ms. Chaplin's assessment of the draft press releases.

On July 22, 2005, Ms. Bonnell prepared for Mr. Tilley two versions of a memo on public disclosure. In it she argues against public disclosure at that time but recommends that patients be notified that there is to be re-testing. She articulates her position on public disclosure in this way:

- As it stands today, we do not know why we are achieving a high rate of conversions in those specimens that have been retested. Is this a case of increased sensitivity due to the new technology that exposes the limitations of the former manual process, or were the tests performed incorrectly? We cannot answer this question, so we risk confusing and upsetting patients and their families and unnecessarily calling into question the professionalism of the lab.

- We cannot say that we have a new piece of technology that is more sensitive and therefore we are retesting old negatives because if we are retesting in this case, why wouldn't we do it every circumstance where new technology improves our ability to diagnose and treat illness? Furthermore,

²³ Transcript of testimony, Carolyn Chaplin, June 5, 2008, pp. 312-314.

to state that this is about technology would be only partially truthful as the organization feels that there is a *possibility* of error that must be investigated. If asked the question, "How did this come to your attention?" then it would appear that our actions were obfuscatory rather than open and honest.

- We have an identifiable group of individuals that we can contact directly. In similar circumstances where, for example, we have lost a batch of specimens or made a quality improvement that impacted upon a group of patients, we have contacted those individuals directly. Regardless of the fact that this is a larger group than we have normally dealt with we must treat these patients with the same regard. In the Health Labrador OB/GYN case, plaintiffs in the class action lawsuit have identified the manner in which they were notified and the loss of anonymity as major militating factors in their decision to sue.

...

A full public disclosure with a press conference, 1-800 information line, letters to all impacted patients and supportive Ministerial comment is not recommended. Legal counsel and risk management advise against such a disclosure, particularly before the impacted patients have had the opportunity to hear about this from us.²⁴

On Sunday, July 24, Dr. Williams chaired a meeting of the Group.²⁵ Its purpose seems to have been to provide an update on the ER/PR problem. By that point the second group of Dr. Carter's re-tests was completed and it was reported that 25 of 32 had converted. Dr. Kara Laing argued for making sure that the Ventana Benchmark was not overly sensitive. This was consistent with Dr. Carter's own concern about whether the Ventana Benchmark might be overcalling. The difference is that in spite of her concerns that the Ventana might be overcalling, Dr. Carter knew that there were other factors contributing to the problem. There was discussion about bringing in representatives of Ventana and comparing Newfoundland and Labrador results using the Ventana with those of other laboratories. Dr. Williams' notes demonstrate the conflict that was facing the Group. He notes "there may be a problem with methodology or with the lab" and "pathologist

²⁴ Exhibit P-1488.

²⁵ Mr. Tilley, Dr. Gardiner, Dr. Laing, Dr. Cook, Mr. Gulliver, Ms. Bonnell, Dr. Kwan, Ms. Predham, Ms. Thomas, Mr. Boone, and Dr. Williams attended.

reporting is an issue,” instead of focussing on the possibility that the Ventana Benchmark might be overcalling. Mr. Tilley’s notes indicate that he was concentrating on what occurred in 2002. He too noted that the Ventana system seemed to be “testing high.”

On July 25, Mr. Abbott asked Mr. Tilley if there was anything new on the ER/PR receptors issue: “Minister is quite keen on this matter.” Mr. Tilley replied that there had been a meeting on Sunday July 24 that included an oncologist and a surgeon. He added: “We are clearly not at a point yet where we can be confident that we have a problem and if so, the extent of it. The physicians are feeling a little more comfortable based on the recent information provided but more is needed to get to the bottom of this.” Who was feeling more comfortable is unclear. Dr. Williams had noted on the 24th that Dr. Alan Kwan “feels happier at this meeting that a large percentage due to technological change.” Mr. Tilley then went on to outline some of the information they were then seeking, particularly in relation to the Ventana.

Interestingly, on July 28, 2005, Dr. Cook and Dr. Carter sent a memo to all pathologists and residents in St. John’s hospitals. The memo contained instructions on optimal assessment and reporting of hormone receptor status in infiltrating carcinoma of the breast. Unfortunately, the memo was not sent to pathologists in other regional health authorities. Many of the points address the failures observed by Dr. Carter in her review. This is important because whatever others were speculating at the time, Dr. Carter and Dr. Cook knew that there was a serious problem and had a good grasp of the underlying reasons.

August 1, 2005: Meeting of the Group and Dr. Carter

I have already spoken about the meeting of the Group held on August 1, 2005, and how important it was in the investigation of the problem. That meeting was also important to the understanding of the problem and therefore what was communicated in the following months. Dr. Carter believed any improvement in technology as a result of the acquisition of the Ventana Benchmarks did not explain the conversions they were seeing. Mr. Tilley’s notes of the meeting include an entry that says:

System error

- Lab equipment
- Pathologists – different pathologists
- Oncologists – turnover

Technology

Should be no difference between DAKO and VENTANA if properly done

- Ventana – less room for error²⁶

In his testimony, Mr. Tilley was vague about the substance of the disagreement that took place at the meeting involving Dr. Carter, Mr. Gulliver, and, to a lesser extent, Mr. Barry Dyer. Mr. Tilley described the debate as being about who owned this issue. Later in his testimony he described the exchange as blaming. Others who attended the meeting, such as Dr. McCarthy and Dr. Laing, did not recall any confrontation. I am satisfied that there was a heated confrontation and that anyone in the room would have known about it.

The discussion between Dr. Carter and Mr. Gulliver did cause some of the Group to think about the position they had been taking. Dr. Carter remembered that someone from the communications division read from a draft document in which there was a statement to the effect that the problem with the estrogen receptor testing was due to the DAKO system and now Eastern Health had a Ventana system that was much more sensitive, implying that the problem was therefore solved. Dr. Carter objected because she knew the statement to be inaccurate. She said, in her testimony:

Just I know that that's not accurate at all, there's no difference between the two machineries, in terms of getting results, it's just knowing how to use the two pieces of machinery. So a very long and very heated debate took place with myself and mainly myself, Mr. Gulliver and Mr. Dyer, to a lesser extent Dr. Williams would jump in every now and then, at which point we agreed that it was not the DAKO system's fault and the Ventana system will be fine.²⁷

This comment is consistent with Mr. Tilley's note.

²⁶ Exhibit P-0548.

²⁷ Transcript of testimony, Dr. Beverley Carter, July 28, 2008, p. 284.

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Ms. Bonnell's notes record "technological change v. lab error." She recalled Mr. Tilley as having chaired the meeting. Her impression, like that of Mr. Tilley, was that there was blaming - in particular, that pathologists and technologists were expressing opinions as to whose fault this was and there was a suggestion that oncologists should have picked up on the problem sooner. She agreed, however, that in that meeting she learned that it was not the machine itself but how the machinery was being used and other processes involved in ER/PR testing that were at the root of the problem, at least as Dr. Carter explained it. In this meeting Mr. Gulliver declared that the Ventana was not more sensitive, just more consistent. Up to this point, the Ventana being more sensitive had figured prominently in the thinking of Ms. Predham and Ms. Bonnell about the problem.

Unfortunately, during the course of the heated discussion between Dr. Carter and Mr. Gulliver, Dr. Carter made a remark that there had been no positive results during a particular period of time. If that allegation had been true, Ms. Predham, for one, would have recognized the far-reaching implications of the statement.

The next day, Mr. Gulliver produced evidence which showed that Dr. Carter's statement about the absence of positive results was not accurate. This encouraged people to discount Dr. Carter's opinion. An example of this can be found in a comment made by Heather Predham about Dr. Carter in an email of November 2006:

As always, Bev's comments in the meeting were a little bit alarmist in nature
....²⁸

Dr. Carter is, no doubt, opinionated. She was not diplomatic in expressing her opinions; her statements could be quite harsh. She is also a skilled pathologist who was attempting to use a logical, scientific approach to assess the ER/PR problem. Within Eastern Health, at the time, it was Dr. Carter who had the most realistic view of the problem. It is most unfortunate that her opinions and advice were so easily

²⁸ Exhibit P-2107.

dismissed. Dr. Carter was right about the Ventana Benchmark and the DAKO Autostainer. Even if the Ventana was overcalling, she knew that was not the answer to the ER/PR problem, although proper validation of the Ventana needed to be done. I am satisfied that Dr. Cook and Dr. Williams also knew this, though in his cross-examination in May 2008, Dr. Williams was still questioning the DAKO Autostainer. The notion that the ER/PR problem could be attributable to machinery continued to influence the thinking and the communications of the Group and others into 2006 and 2007.

Early August 2005

As noted earlier, on August 2, 2005, Dr. Carter resigned from her work on the re-testing. Consequently, the Group had to turn its attention to the development of a revised plan to deal with the ER/PR problem. Within a week, arrangements had been made to have both the prospective and the retrospective work done at Mount Sinai. The Ventana representative had inspected the Ventana Benchmark and provided a report which effectively stated that the Ventana Benchmark was operating within specifications. Arrangements had already been made to have Ms. Trish Wegrynowski come from Mount Sinai to review the laboratory procedures. On August 2, Dr. Cook made the first contact with Dr. Diponkar Banerjee, who eventually did a pathology review for Eastern Health. Eastern Health was also taking steps to address some of the weaknesses that had been identified. For example, Dr. Ejeckam was formally named as the resource person for immunohistochemistry. Ms. Predham did her interviews with the IHC technologists.

Dr. Cook met with two different groups of pathologists, primarily from the General Hospital, to apprise them of the existence of the ER/PR situation and let them know a retrospective review was to be conducted. These meetings occurred on August 1 and 5, 2005. He told them that a significant number of conversions had occurred in the cases retested to that point. Dr. Cook recalled that during those meetings, the pathologists in attendance were stressed and anxious, though the level of emotion lessened after he reassured them that: the work of everybody, including himself, would be included in the review; and based on what was then known the problem seemed to be widespread and not limited to any one

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hospital. Those present sought assurances that the reviewer would not know the identities of the pathologists who had originally reported the cases being reviewed. Dr. Cook told them the review was not intended to single out any one or more pathologists. He also told them he would keep them apprised as much as possible as the review went forward.

On Friday, August 5, Mr. Tilley and Dr. Williams met with Mr. Ottenheimer again. Mr. Abbott; Ms. Moira Hennessey, Assistant Deputy Minister, Regional Health Operations; and Ms. Stephanie Power, a communications specialist, also attended that meeting. Mr. Tilley's notes indicate that the Minister was being advised about the many things that had occurred that week, including using Mount Sinai for the retrospective and the prospective work, the visit by the Ventana representative and the external review to be done by Dr. Banerjee. Three points relevant to the issue of communications with patients were made by Eastern Health. The first was that in the future, testing would be done at Mount Sinai. This information eased the Minister's concern about the accuracy of current testing. The second was that the oncologists had been consulted and were opposed to telling patients that they were going to be re-tested.²⁹ They believed it would be preferable to wait until the results were available to tell the patients. The third was that Eastern Health did not yet have sufficient information to begin notification. In the end, as with the meeting of July 21, Eastern Health was left to gather more information. Ms. Hennessey's notes add that patients who had no change in results would not be contacted. She also recorded that the estimate of the number of re-tests for a 5-year period was 500.

However, at a meeting within Eastern Health on that same day, August 5, consideration was being given to notification of patients. That meeting, held at 4:15 p.m., was attended by Dr. Williams, Ms. Pilgrim, Dr. Paul Gardiner, Dr. Laing, Ms. Predham, and Dr. Cook. In his notes of that meeting, Dr. Cook records the retrospective as starting at March 31, 2004, and going backwards.³⁰ Dr. Williams' note said: "all patients seen

²⁹ Dr. Laing said in her testimony that the first occasion she recalls having discussed her view of the idea of sending a letter to patients was August 10.

³⁰ This would cover the period before the use of the Ventana.

in the clinic since April 2003³¹ that are negative are being retested,” but Ms. Predham records it as “May 1997 until now.” Ms. Predham does have a reference to March 31, 2003, which is crossed off. Ms. Predham’s note also states:

Notified by their physician following them for their cancer - appointment made to discuss the results.

Reports will have to come to a central area. Determine

1. Cancer Centre patients
2. If not, who is following them - or phoned patients³²

These notes indicate that the attendees were anticipating how patient notification would be handled when re-test results were received. Dr. Williams’ notes say that Ms. Predham is charged with identifying the patients who are to be re-tested. Ms. Predham, however, is very clear that that was not her responsibility: Mr. Gulliver and Dr. Cook identified the patients and pulled out the blocks to be sent. Mr. Gulliver and Dr. Cook were pulling blocks for the period from 1997 to 2004 at that point. Ms. Predham saw her role as preparing a list of those patients and checking that list against other sources of information, such as information from the Cancer Registry.

The notes of this meeting illustrate how the failure to keep minutes or even track decisions has made the reconstruction of events difficult. Many of the witnesses did not have independent recollections of the meetings and relied on their notes when testifying. Often the notes conflicted with those of someone else in the room. More importantly, the failure to keep records may have contributed to misunderstandings as decisions were being made. Very few of the people dealing with the ER/PR problem had any real understanding of IHC testing. It would be unrealistic to think that everyone in the meetings was going to understand all that was said. No doubt these individual notes were also used by members of the Group when they were dealing with the problem. If there had been an official record of at least the decisions

³¹ April 2003 would have been around the time Dr. Ejeckam intervened to halt ER/PR testing.

³² Exhibit P-2954, pp. 8-9.

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made and the rationale for them, there would have been less confusion both when the problem was being dealt with and now.

On August 8, 2005, in an email to other members of the Core Group and Ms. Pilgrim, Ms. Predham raised again the question of the patients from Saint-Pierre and how to inform or provide a hotline service for them. She also referred to the preparations for putting a hotline in place, including the preparation of answers to questions likely to be asked by patients. She adds:

Also, will we be informing GP's of this issue? I think Kara Laing suggested that the letter use wording like "you will be notified by the physician following your cancer and an appointment made to discuss results."³³

On August 8, Ms. Predham forwarded to the members of the Quality Department the draft FAQ (frequently asked questions) and anticipated answers. The first question and answer were as follows:

I was tested for ER/PR Receptor between 1997 and 2004[.] What does this mean to me?

This would be [to] reiterate the information in the letter:

Due to improved technology and the discovery of inconsistent results, Eastern Health has begun retesting a select group of breast cancer patients whose results indicated that they were negative for ER and PR.

Your previous test results indicated that you are negative for ER and PR and as the presence of these receptors helps determine the most appropriate treatment of breast cancer, your previously collected tissue sample will be retested. Although we are retesting your tissue sample, this does not mean your treatment will change at this time. We need to confirm the validity of your previous test results.³⁴

The response shows that a week after the August 1, 2005, meeting, notwithstanding Dr. Carter's comments, the notion of improved technology being a reason for the re-testing remained part of the communication plans of Eastern Health.

³³ Dr. Laing could not recall giving any suggestions as to wording for a letter that was to go to patients; Exhibit P-0558.

³⁴ Exhibit P-0785.

On August 9, 2005, Mr. Abbott made another inquiry of Eastern Health. This time he directed the inquiry to Dr. Williams:

Just checking in to see if the letters to the patients respecting re-testing of negative ER/PR test results are being sent. Please advise. Meanwhile, thanks for your continued assistance/advice in this matter.³⁵

On August 10, 2005, Mr. Tilley, Dr. Williams, Dr. Cook, Dr. Laing, Ms. Predham, Ms. Pilgrim, and Ms. Bonnell met. In that meeting, the question of communication with the patients was discussed again. Mr. Tilley reported on his last meeting with the government and the Minister's position that a letter should be sent to patients. Dr. Laing advocated delay. She did not want to send out letters to the patients until the size of the problem was more clearly defined. She argued that it would create unnecessary anxiety for a lot of patients to tell them before the results were back. Dr. Laing characterized the problem as striking a balance between waiting and giving good information and causing undue anxiety. At that point she believed that the results of the re-test would take four to six weeks to come back from Mount Sinai. If they waited for those results, a physician could sit down with the patients whose results had changed, and explain the implications of the changed result for each patient. With the benefit of hindsight, however, she said:

Looking back, knowing what I know now that, in fact, it took much longer for Mount Sinai to get through the test results, it took much longer for us to do the panel because honestly at that point I was not expecting the volume of work that was generated from this, then I would have, I would have changed my mind on that issue and I would have said, yes, knowing -- and this is, you know, and this is the issue with disclosing things like this to patients, there are some people who, you know, want to know right away and there are some people who would say, I would like to know what that means for me. It was always our intention to disclose to patients. The big question was the timing.³⁶

Dr. Laing did not recall the positions of anyone else in the room. She was only able to say that she did not recall anyone strongly

³⁵ Exhibit P-1431.

³⁶ Transcript of testimony, Dr. Kara Laing, September 10, 2008, pp. 229-230.

disagreeing with her view. At some point she was told that the Minister had a different view. Later in her evidence she added:

You know, really when I look back at that time, my position was go to the patients individually with as much information as we could at the time. Again, back to the point that I thought that this was going to be over four to six weeks. One of the things that I was concerned about, and of course, you know, we're still in August of 2005, and we really have no idea what the actual magnitude of this is going to be. Now, of course, looking back, we know that more, but even at this time, we weren't sure that this was going to be something that affected very many patients and so you're trying to balance, you know, causing anxiety in a large group of people versus waiting until you have that information to be able to give to the patients, and really, in one step, if you will, address the issue.³⁷

Dr. Laing stated that her opinion reflected that of other oncologists. She acknowledged that oncologists were concerned that if there were to be a mass notification to patients, the many phone calls from patients and the added questions during visits would interfere with the oncologists' ability to handle the workload.

Aside from the discussions with the Minister, Eastern Health did not at that time seek the advice of anyone outside a small number of people within its own organization on whether or how to disclose to patients. Much later, in June 2006, there was an ethics consultation on the question of disclosure to families of the deceased, an issue Eastern Health had put aside at this point. Eastern Health did not consult patients who had earlier been told of changed results, nor the ones with metastatic disease whom oncologists were telling about their results as they were re-testing. The Canadian Cancer Society was not consulted on the point. In short, when the discussions were being held about disclosure of this information to patients, there was no one to advocate for the patients. Those within Eastern Health who argued that they were putting the interests of the patients first cannot be said to have been without bias in the circumstances.

³⁷ Transcript of testimony, Dr. Kara Laing, September 10, 2008, p. 246.

Had anyone solicited the advise of breast cancer patient advocate, Ms. Geraldine Rogers, she would have taken strong exception to the idea of delaying informing the patients so as not to cause them anxiety and stress.

The Patient's Perspective on Disclosure: Geraldine Rogers

What kind of rabbit hole?

Ms. Geraldine Rogers of St. John's was diagnosed with breast cancer in Carbonear, Newfoundland, in June 1999.

On June 30, 1999, Dr. Gary Baker entered an addendum to Ms. Rogers' pathology report, noting her to be ER negative and PR positive 60-70% of cells.

Ms. Rogers was treated at the Cancer Centre by Dr. Kara Laing. On May 12, 2000, Dr. Laing had a lengthy discussion with Ms. Rogers about tamoxifen. They discussed the evidence of tamoxifen's benefits to PR positive patients and the fact that the treatment may be more beneficial for a patient with a positive ER result. Ms. Rogers decided against anti-hormonal treatment after consulting an oncologist outside the province who suggested that because she was ER negative, she should not take tamoxifen.

On August 11, 2000, Dr. Laing's Progress Note on her chart stated: "When I last saw her, we discussed at length tamoxifen. She has decided not to take this. She is too worried about its side effects. I think given the fact that she is ER negative and only about 20-25% PR positive that this is ok."³⁸ The source of this level of PR positivity is uncertain; however, after this statement is made, there are several references to Ms. Rogers' hormone receptor status as ER negative and PR "low positivity."

In November 2002, she underwent a prophylactic mastectomy of her right breast. At that time there was a diagnosis of DCIS. It appears no ER/PR test was carried out then.

³⁸ Exhibit C-0126.

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She first heard of the ER/PR re-testing issue through the *Independent* story on October 2, 2005. She was not pleased to learn of this through the media. She made several attempts in October 2005, after hearing of the issue in the media, to elicit information about the re-testing process from the Department of Health and Community Services and Eastern Health. She left messages at Eastern Health, saying that she was calling about the ER/PR issue. None of her messages were returned. She also left messages for Dr. Laing which also went unreturned. Ms. Rogers found this to be out of character for Dr. Laing, with whom she has always enjoyed a good relationship and whom she has always found to be accessible. Ms. Rogers is well known in this province as an advocate for breast cancer patients. She was being approached by the media at the time to give interviews and she wanted to be well informed on the issue before speaking publicly.

In the fall of 2005, Ms. Rogers had a discussion with her family physician in which her doctor expressed concerns about physicians' level of knowledge of the ER/PR issue. Ms. Rogers asked her doctor if she knew anything about what was going on and her doctor replied that she did not. Her doctor stated that she had not been contacted at all and she was receiving inquiries from patients that she could not answer. She asked Ms. Rogers to let her know if she was able to find out any information. Ms. Rogers was astounded that the family physicians had not been contacted and provided information to assist them in answering their patients' questions. The failure to provide information to the primary care physicians was a major weakness in the handling of the ER/PR issue. It is extremely important to ensure the medical community is well informed and kept apprised of what is happening, particularly with respect to such a large-scale adverse event.

Ms. Rogers was also of the view that a letter to patients would have been a good way to explain the situation, as there was a lot of confusion circulating about the issue.

Dr. Laing saw Ms. Rogers for a regularly scheduled visit on December 6, 2005. Dr. Laing wrote the following in the Progress Note that day: "She was initially ER negative PR positive; on re-testing a lot of

patients with this profile have come back as ER and PR positive. Her re-testing has been sent off but I do not have the results yet.” Ms. Rogers inquired of Dr. Laing why nobody had contacted her. She testified that Dr. Laing told her she had wanted to tell the patients. Dr. Laing denied she had said this to Ms. Rogers.

Ms. Rogers criticized as paternalistic the notion of withholding information from patients to spare them stress:

It’s not 1955. It’s 2005 and we’re grown adult women. Many who have been--who’ve had surgery, who’ve had horrible chemotherapy, who’ve gone through radiation, and that we’re adults, and we’re smart, and we take part in our health care. We have to make decisions...³⁹

In January, she heard through the media that all the results were back but she still had not heard about her re-test. She again phoned Eastern Health on January 25, 2006, and left a message. Nobody returned her call. On January 26, 2006, Ms. Rogers’ case was reviewed by the Panel. The Panel minutes state that no change in treatment plan is recommended as the patient had been initially prescribed tamoxifen by her oncologist but did not take it. Ms. Rogers’ decision at that time had been based on the understanding that she was ER negative. She is adamant that if she had known she was ER positive in 2000, she definitely would have taken tamoxifen. It is indeed troubling that the Panel would base many of its recommendations on historic decisions made by patients at a time when they did not have accurate information. Obviously, patients should have been provided with all of the facts and allowed an opportunity to reconsider their options in light of the new information.

On January 27, 2006, Dr. Laing wrote a panel letter to herself regarding Ms. Rogers. It is somewhat peculiar in that the letter contains no recommendation at all.

Ms. Rogers called Eastern Health again on February 6, 2006. On that date she spoke with Ms. Nancy Parsons. Ms. Parsons subsequently

³⁹ Transcript of testimony, Geraldine Rogers, March 25, 2008, pp. 155-156.

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emailed Dr. Laing and Ms. Predham and advised them she had just spoken with Ms. Rogers, who voiced concern about the way patients were being treated. She complained that she had not received the results of her re-test. According to Ms. Parsons' note, Ms. Rogers told Ms. Parsons that she would be contacting Mr. John Ottenheimer, then Minister of Health and Community Services. Ms. Rogers did indeed speak with Minister Ottenheimer and relayed her concerns to him. Within an hour of her discussion with the Minister, she received a phone call from Dr. Laing, who was out of the country at the time. Dr. Laing told her in that telephone discussion that her results had changed.

Ms. Rogers recalled that her discussion with Ms. Parsons had taken place after she had already spoken with the Minister and Dr. Laing. She recalled that Ms. Parsons apologized for not having called her back. She explained that it was her job to contact the patients whose results had not changed. Patients whose results had changed were to be contacted by their physicians.

On February 17, 2006, Dr. Laing saw Ms. Rogers again and they discussed the change in her results. The Progress Note for that visit states that, "She was presented at the panel about two weeks ago. It was recommend[ed] that she be considered for tamoxifen or an Aromatase inhibitor."⁴⁰

Several weeks after the paneling of Ms. Rogers' case, on March 9, 2006, Dr. Donald Cook entered Ms. Rogers' changed ER/PR results on her chart.

Ms. Rogers consulted the same expert from outside the province whom she had contacted in 2000 about taking anti-hormonal therapy. That doctor recommended that, given the passage of time, she should not commence anti-hormonal therapy. On May 16, 2006, seven years after her original diagnosis, Ms. Rogers advised Dr. Laing of her decision not to take the treatment and Dr. Laing recorded in the Progress Note of that date that she "was okay" with the decision not to take Arimidex this long after diagnosis.

⁴⁰Exhibit C-0138.

Since the ER/PR issue became the subject of public discussion, Ms. Rogers has been interviewed extensively by the media on the issue. In an email to Mr. George Tilley and others within Eastern Health on May 16, 2007, Ms. Susan Bonnell, Communications Director of Eastern Health, referred negatively to Ms. Rogers and others. Ms. Bonnell was trying to convince the executive of Eastern Health to speak publicly on the ER/PR issue. She wrote, "Our credibility as an organization and our ability to provide quality care are being maligned... When you don't speak, the story continues, with or without you and the media look for less credible spokespeople who will speak to them; hence, Peter Dawe, Geri Rogers..." Ms. Rogers was shocked to read this. She said, "I looked at this and I thought, what kind of rabbit hole have I fallen into where it's all topsy-turvy and we're the bad guys."⁴¹

Mid-August 2005

As noted above, Dr. Laing stated that had she known the re-testing would take so long, her view on patients being told that there was to be a re-test would have been different. She explained her position this way:

No, I think that we realized if this was going to go on for a longer and longer period of time, that you would be getting back to the point that you raised earlier that if we're telling, you know, two or three patients this week, two or three patients next week, that eventually this would be something that would get out there, in terms of being common knowledge within the clinic or within support groups and all that sort of stuff. To this point, you know, although there had been patients disclosed to, it was a very, very small number. We didn't know what, at the end of the day, was going to be the number of patients that were going to be disclosed to, and I guess I can only answer that in terms of what I recall to be my thinking at the time, or the reason for wanting to wait.⁴²

A couple of days later Dr. Williams asked Dr. Laing to meet with the Minister and give her opinion of the proposal to send letters to the patients before the re-testing was done.

⁴¹ Transcript of testimony, Geraldine Rogers, March 25, 2008. pp. 196-197.

⁴² Testimony of transcript, Dr. Kara Laing, September 10, 2008, pp. 272-273.

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On August 12, 2005, Ms. Bonnell produced for Mr. Tilley and Dr. Williams a document entitled *Communications Options ER/PR testing at St. John's Hospitals*. The primary purpose of the document was to provide a succinct statement of the strengths and weaknesses of various options relating to disclosure. It was in many respects an update of her memo of July 22, in which she recommended against public disclosure at that time but suggested that patients be contacted in advance of re-testing to advise them that re-testing was to be done.

In the August 12 document, Ms. Bonnell considered three options: media release, patient letter, and individual patient notification. While Ms. Bonnell pointed out why media releases are beneficial, she concluded that a media release is appropriate only in the context of a need to disclose an error or to find a way to reach a large, general group, neither of which she believed to be the case for Eastern Health. The document states that they do not know if there was a "system failure" and that they know the names and addresses of those they have to contact. She concludes that there is nothing to be gained by going public: "There is very little that can be done in this circumstance to avoid criticism; even if we had immediately acted on this issue publicly we would be criticized regardless." Ms. Bonnell seems to have concluded that by that point the opportunity to control the message through a public announcement had passed.

As to a patient letter, meaning a letter sent to a patient advising that there would be re-testing, Ms. Bonnell recognized that, given the numbers, this was a practical alternative to individual contact prior to re-testing. She then set out the weaknesses of the approach she had recommended less than a month before:

Originally, we proposed sending letters when we believed that the specimens could all be retested within two weeks. Given the fact that our Ventana system is now being reviewed as well, we must send the specimens to an independent laboratory. This delay while not considered significant by the Oncologists, would be an unnecessary hardship for any patient who had been notified that their tissue was being retested and that their treatment may change.

Our medical specialists do not want us to send letters to all patients. They believe that each patient must be treated individually - in fact, some patients

may already be taking Tamoxifen or would not be given this drug regardless of their ER/PR status.⁴³

This analysis pulled together two points: the potential anxiety that might result from uncertainty about whether there might be a change in treatment, and the fact that a changed result on the test might not result in treatment change.

Ms. Bonnell then turned her attention to individual patient notification. While Ms. Bonnell does not describe how this would occur, I infer that she is here speaking of some person from Eastern Health contacting each patient after the re-tests are completed. It is not clear whether she was thinking of notifying all patients or just the ones whose treatment was to change. One of the advantages of this approach is said to be that it does not cause undue stress to breast cancer patients and their families who are unaffected by this particular situation. The weaknesses are:

It is highly likely that, as the number of patients whose treatment is affected increases, the issue will reach the public forum. Someone will go to the media and we will have to react to this as a media story.⁴⁴

Ms. Bonnell then gave examples of the type of questions from the media they would likely face if the public became aware of it in this manner. She also added key messages about various aspects of the problem and attached a draft patient letter. The draft letter says, in part, "Since your tissue was first tested, there have been improvements in technology and changes in the approach to offering hormone therapy. In addition, upon review of our procedures we have noted some inconsistent test results that have led us to the decision to retest your tissue sample." The first cited reason is improved technology and the second is inconsistent test results, which are said to have been noted "upon review of our procedures." One of the key messages contained under the heading "understanding immunoperoxidase staining" is:

⁴³ Exhibit P-0331, p. 3.

⁴⁴ Exhibit P-0331, p. 3.

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- From 1997 to 2004 our laboratory used a process for immunoperoxidase staining called the Dako system. This technique required the manual boiling of tissue and measuring of minute mixtures of re-agent. The Dako test was implemented in 1997 to replace a bioassay method for ER/PR receptors. While used nationally with some success, this process leaves room for error and we have had challenges with the process in the past.
- The Ventana method (installed in April 2004) automates this process removing as much manipulation as possible. In addition, all re-agents used on the Ventana system are quality controlled by the company and arrive in the laboratory as “ready for use.” The Health Sciences Centre was one of the earliest laboratories to obtain the Ventana system and switch to an automated system.⁴⁵

Ms. Bonnell argued in her August 12 memo against sending such a letter. However, the draft patient letter seems to be contrary to the position taken by Ms. Bonnell on July 22 when she argued that Eastern Health could not, at least in the context of a public disclosure, say they were re-testing because they had new, more sensitive technology, and further they did not know if this was a case of more sensitive technology or if the tests had been incorrectly performed.

On August 15 another meeting took place with Mr. Ottenheimer. This time the representatives of Eastern Health were Mr. Tilley, Dr. Williams, Dr. Cook, and Dr. Laing. Along with the Minister there was Ms. Chaplin; Dr. Blair Fleming, Assistant Director of Physician Services; and Ms. Hennessey. Mr. Ottenheimer was told that there would be approximately 400 patients re-tested⁴⁶ and that Mount Sinai would need six to eight weeks to do the re-testing. He was also told about the two consultants who were to come in September. Dr. Williams’ notes are the most detailed about Dr. Laing’s presentation. Interestingly, it was Dr. Laing, not Dr. Cook, who was suggesting that the results to that point might not truly represent the size of the problem because the sample tested had been biased and, in any event, on re-testing a certain

⁴⁵ Exhibit P-0331, p. 4.

⁴⁶ Ten days earlier Ms. Hennessey had recorded that there would be 500 re-tests done for a five-year period. Both were underestimates and that should have been known within Eastern Health.

percentage of results would convert.⁴⁷ Dr. Williams' note indicates that Dr. Laing made the point that she did not "feel now is the time to write the letter. Better to wait until we have more information." The Minister was said to have expressed the view that if people were advised as soon as possible then "a patient can do what she or he wants to deal with the issues." Dr. Laing added that Dr. McCarthy and Dr. Pradip Ganguly agreed with waiting until they had more information before sending something out. At the conclusion of the meeting the Minister agreed to accept the advice "for now," asked for a meeting in two weeks, and expressed the view that the letter should be developed in the meantime. Reading Dr. Williams' notes, one might conclude the discussion was about a letter telling patients they were going to be re-tested.

Dr. Laing's recollection of what she told the Minister on this occasion is somewhat different from what is reflected in Dr. Williams' note. She recalled that she was saying "let's get the retesting done and then sit down and go over the results with the patients." Mr. Ottenheimer's recollection is consistent with that of Dr. Laing on this point. Ms. Hennessey was quite firm in her recollection that Dr. Laing, who was representing the oncologists, felt that the disclosure to patients should be after the test results came back and that disclosure should be done by the attending physician. Dr. Laing did not focus on the fact that the Minister was being told that the period of time for re-testing was six to eight weeks. She was still thinking four to six weeks, but the difference probably would not have influenced her opinion.

It was the advocacy of Dr. Laing that caused the Minister, if not to accept the position that patient notification should await the return of re-test results, to allow himself to be persuaded, once again, that any notification to patients could be delayed. Dr. Laing's position was based on certain assumptions:

1. that the results of the re-testing would be back from Mount Sinai in 4 to 6 weeks;
2. that they did not know the magnitude of the problem; and

⁴⁷ Dr. Laing's opinion was that this referred not to the general concept of there being a number of false negatives but to the experience with re-testing to that date.

3. that they were not sure it was going to affect very many people.

She acknowledged that she had not considered that the matter might become public knowledge before the results were returned.⁴⁸ Her recollection was that she had no further involvement in the issue until the end of September. She said that Dr. Williams never indicated that he did not agree with her view on patient disclosure.

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After the meeting of August 15 and the decision not to communicate with the patients at that time, very little activity related to communications was recorded. On September 1, Ms. Hennessey emailed Mr. Tilley inquiring when there might be a further update for the Minister. Mr. Tilley replied, telling her that in excess of 200 blocks, “approximately 50% of the total,” had been sent to Mount Sinai and the first results were expected on September 10. He gave the dates the external experts were to visit and noted their reports were expected by mid-October. Ms. Hennessey seemed to be satisfied with this report but she added that she and Mr. Abbott were seeking to arrange another briefing for the Minister to be held after September 10, when Eastern Health would have some results. She added; “We also need to know when Eastern Health is going to notify patients as part of the briefing.” Mr. Tilley agreed to arrange the briefing and Ms. Hennessey said she would contact him the next week to arrange the timing. In fact, the next meeting between officials of Eastern Health and the Minister was called hastily in early October, after the matter became public.

On September 21, 2005, there was a meeting of the Board of Trustees of Eastern Health. The minutes indicate that the Board was advised that “the organization made a decision not to release any information publicly until the results of the retests were available.” There is nothing to indicate when that decision was made or who made it. Dr. Laing, who had attended the August 15 meeting with the Minister, did not believe any decision was made there regarding communications.

⁴⁸ “When I think back to that time, that wasn’t something that had crossed my mind, no.”

The notes of those who attended the meeting support the inference I have drawn, that at the conclusion of the August 15, meeting, as with the earlier meetings with the Minister, there was no resolution to the question of communications with patients or public. The issue was merely put off for another two weeks. Ms. Hennessey's comments around the first of September suggest that the Department of Health and Community Services was still expecting some type of patient notification before the re-testing was complete.

On Friday, September 30, 2005, Strategic Communications received an inquiry from Ms. Clare-Marie Gosse of the *Independent* newspaper. Ms. Gosse told Eastern Health that she had heard that one of the mammography units at the Health Sciences was faulty - it had produced inaccurate results, and women who had been tested were being recalled for further testing. By coincidence, when this inquiry was received Ms. Predham and Ms. Bonnell were meeting in Ms. Bonnell's office. Ms. Bonnell recalled that they were discussing the draft letter to patients to advise them that they had been re-tested. Ms. Predham recalled that now that test results were beginning to come back, she and Ms. Bonnell were considering some scenarios for communicating with patients. The idea was that these scenarios could be presented to the Group to focus the discussion regarding disclosure to patients. While it was sometimes said by officials of Eastern Health that this meeting between Ms. Predham and Ms. Bonnell was a part of a plan by Eastern Health to inform its patients, I am satisfied that this was an effort by two individuals to try to do something about the inertia that had set in around the question of patient notification.

Ms. Bonnell was that while the details were incorrect, Ms. Gosse was in fact referring to the ER/PR story. Ms. Bonnell called Dr. Williams. She was not sure whether she also spoke to Mr. Tilley. Her advice was that they could not allow an incorrect story about mammography to be published. She advised that Ms. Gosse be told the true story. That advice was followed. Ms. Bonnell asked Ms. Gosse to hold the story until patients could be contacted. After consulting with her editor, Ms. Gosse said the *Independent* would be running the story. Ms. Bonnell then, with

the assistance of Dr. Williams, arranged for Ms. Gosse to speak also with Dr. Laing.

Another request for information, this time from NTV, a television station of the Newfoundland Broadcasting Company Ltd., came in on the same day. Ms. Bonnell's response was that Eastern Health could not provide anyone to respond until Monday. Consequently, the story first broke in the *Independent*.

Ms. Bonnell says that at this point she would have advised Ms. Tansy Mundon, the Director of Communications, Department of Health and Community Services, that the story would be breaking. In fact, it was Ms. Chaplin, who was then Director of Communications, Communications and Consultation Branch, Executive Council, whom Ms. Bonnell reached.

At 1:45 p.m. on September 30, 2005, Ms. Predham emailed Ms. Bonnell, attaching a draft briefing note. Later that afternoon that note, as amended, was sent by Dr. Williams to Ms. Hennessey. The background information contained in the note is essentially the same as that given by Ms. Predham to the other regional authorities the day before, when she reminded them to send in their patient samples, since the first re-test results were back. In this briefing note Ms. Predham also provided more information about the visit of the Ventana representative. As to the visits of Dr. Banerjee and Ms. Wegrynowski, Ms. Predham stated that peer reviews were conducted, a debriefing had taken place for each, and a full report from each was expected within a few weeks. The balance of the September 30, 2005, briefing note provided details of the re-testing being done at Mount Sinai.

Late in the afternoon of September 30, 2005, Ms. Chaplin emailed a number of people, including Ms. Matthews and Mr. Thompson, telling them that she had been advised by Eastern Health that the ER/PR story was about to break.

The *Independent* story was published on October 2, 2005. It quotes two sources of information within Eastern Health: Dr. Laing and Ms.

Bonnell. Dr. Laing was in Toronto on September 30, 2005, attending a meeting. Dr. Williams tracked her down at the meeting, explained the situation, and convinced the reluctant Dr. Laing to do the interview. Dr. Laing was uncomfortable with talking to the reporter over the phone, but she was advised that the interview could not await her return from Toronto. She was also uncomfortable because for prior interviews she had always first been prepared for the interview by someone from Strategic Communications. She recalled trying to convince the reporter not to run the story until patients had been informed but felt that the reporter was not interested in her concerns.

By the time of the interview with Dr. Laing, Ms. Gosse knew that this story did not concern mammography; rather it was about hormone receptor testing. Dr. Laing explained how the test was used. In her article, Ms. Gosse quotes Dr. Laing as saying:

The reason why we haven't gone public with this is we don't have all the answers. ... The last thing that you want to do or we want to do is to make people afraid ... is to cause some sort of mass hysteria.⁴⁹

Dr. Laing had no quarrel with these quotes except that she does not believe she used the phrase "mass hysteria." Ms. Gosse attributed to Dr. Laing the statement that new information surrounding the hormone receptor tests led to the decision to conduct the review. Dr. Laing is then quoted as having said:

There were one or two patients that had had retesting done for another reason, where we noticed sort of a difference... we notice some discrepancies and there was a thought that maybe there was something going on.⁵⁰

Dr. Laing explained that here she was thinking of the information from Dr. Clifford Hudis having caused them to look at cases of lobular cancer and how they then moved to consider whether other patients with other types of cancer should be re-tested. Ms. Gosse reported that Dr. Laing had said that patients found to have inaccurate readings would be able immediately to discuss with their physician any necessary changes

⁴⁹ Exhibit P-0086.

⁵⁰ Exhibit P-0086, p. 2.

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to their treatment. As to the number of patients affected, Dr. Laing is quoted as having said:

Of the ones that have been coming back ... I looked at maybe, I don't know, 40 or 50 the other day and there were five or six people that were there, that it may have had an impact, so it's not a huge thing.⁵¹

In her testimony Dr. Laing stated that when she spoke of five or six people perhaps she was referring to the first group from Mount Sinai. When one examines the re-tests that had been returned to Eastern Health before September 30, 2005, it is clear that far more than five or six people were affected, whether one looks at the number whose test results changed or the number who ultimately had recommendations for treatment change. Nor does the data support the idea that Dr. Laing was thinking of the re-tests done by Dr. Carter. I could find no reasonable explanation for Dr. Laing's statement to Ms. Gosse regarding the number of people affected.

Ms. Gosse's article also included the following:

Susan Bonnell, spokeswoman for the health care corp.,⁵² says a new, more accurate piece of equipment was installed in the laboratory last year, providing clearer results and current hormone receptor tests are also being double checked as part of the quality review. She adds the retesting is not impacting patients waiting for other laboratory results.⁵³

The *Independent* story was important. First, the question of making the issue public was taken out of the hands of Eastern Health. Second, it required that the communications plan now be revised, and third, the public, including patients, were provided with their first information on the subject.⁵⁴

Mr. Ottenheimer said that when the story broke in the *Independent*, he "felt a sense of relief, it's out there, it's now public information, the

⁵¹ Transcript of testimony, Dr. Kara Laing, September 10, 2008, pp. 364-365.

⁵² Healthcare had ceased to exist by this time.

⁵³ Exhibit P-0086.

⁵⁴ There were, of course, a few patients who had been advised of changes in results after the in-house re-testing during the summer of 2005.

key being that individuals can do what they please once they are provided with the information.”

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Within Government, the publication of the *Independent* story caused a reaction in the Department of Health and Community Services. On Monday morning, October 3, “central government” called early to look for a briefing note. Mr. Abbott called Eastern Health seeking an immediate meeting. Ms. Hennessey recalled Mr. Tilley and Dr. Williams came. She was tasked with preparing the briefing note for central government.⁵⁵ Ms. Hennessey edited slightly the briefing note prepared by Eastern Health on September 30 and added some new information, most of which was obtained in the meeting on the morning of October 3. Ms. Hennessey used the numbers provided in the briefing note of September 30. They specified the number of patients whose treatment could be affected, rather than the number of changed results. This information was provided by Eastern Health on the morning of October 3. Ms. Hennessey recalled that normally when numbers came into the Department from an agency she would do an independent analysis of them, but in this case she was instructed by Mr. Abbott to accept the numbers provided by Eastern Health. She chose to use the written record rather than the number provided by Dr. Williams from memory. As to the question of contact with patients, Ms. Hennessey recorded that for those patients whose treatment might be affected, Eastern Health would send a letter to the surgeons and other attending physicians and the physicians would determine the follow-up actions for the patients. Although the note says that the focus would be on informing physicians of living patients, nothing was said about communications with the many others who would have had re-testing but whose results or treatment did not change.

Ms. Hennessey’s note went to Cabinet Secretariat, where it was reviewed and added to by others, who then sent it, as a Cabinet Secretariat briefing note dated October 5, 2005, to a number of people, including the Premier, Mr. Crawley, Ms. Matthews, and Mr. Thompson.

⁵⁵ Here this means Cabinet Secretariat and the Premier’s Office.

Within other regional health authorities, attention was being paid to ER/PR as well. Having advised them on Friday, September 30, that the story was likely to break, Ms. Predham advised Ms. Judy Budgell, of Central Health, and Ms. Susan Sullivan, then the risk manager at Western Health, on Monday morning that the *Independent* had run the story and that she would be in touch later that day or on Tuesday with details about what Eastern Health was going to do “in case you want to do something similar.” In Grand Falls a summary of the activity of the Central West Health Centre related to ER/PR was prepared. In an interesting note of realism, the author states “as of Oct 3rd it is estimated it could take as long as 3-4 months to process and test all specimens at Mount Sinai hospital in Toronto.”⁵⁶ Dr. Maurice Dalton provided Ms. Budgell with the details of his laboratory’s response to Eastern Health’s requests for re-testing. Later that morning Dr. Alteen replied directly to Ms. Predham, relaying the information from Dr. Dalton and stating that, contrary to what was said in Ms. Predham’s earlier email, Central Health had made every effort to comply with the requests of Eastern Health in this matter.

Dr. Alteen also spoke to Ms. Bonnell on October 3. His notes state that there would be no press release by Eastern Health, and that frequently asked questions and the contact information for the patient liaison officer would be posted on Eastern Health’s website. Dr. Alteen also noted two interesting statistics: less than 10% of breast cancer patients would be affected and 25% of patients who are negative will change to positive.

Just before 3 p.m. on October 3, Ms. Mundon reported to Mr. Abbott; Ms. Hennessey; Dr. Ed Hunt, Assistant Deputy Minister, Medical Services; Mr. Hynes; and the Minister, confirming earlier information about the media activity of the day and addressing the question of a news release by Eastern Health. Ms. Mundon wrote:

John, I discussed with Susan the merits of doing a news release. She advised that the strategy in July was that they would notify patients before they went

⁵⁶ Exhibit P-1950.

public so they decided against a news release. She indicated she had the support of the department with this approach. They now felt that “the horse has left the barn” and that the media that were interested in the story have already covered it.

I requested for Frequently Asked Questions be posted to the website so that people would have easy access to information. I tend to agree with Susan this time with the news release. It seems as[if] the opportunity for a news release to be issued in proactive manner has past [passed]. I believe we should continue to monitor the coverage and the reaction. If we did issue a news release at this point, it would be picked up by local newspapers and would probably draw attention to the issue unnecessarily.⁵⁷

The Frequently Asked Questions (FAQs) about ER/PR posted to Eastern Health’s website included the following:

What is happening now? Why are some test results different?

Eastern Health has begun retesting a select group of breast cancer patients – those whose results indicated that they were negative for ER and PR. In 2004, the lab at the Health Sciences that does all of the ER and PR testing for the province introduced a new piece of technology and we discovered some inconsistent results from the old system.

This has prompted Eastern Health to re-test all the negative ER and PR receptors results since 1997 to ensure that all patients have every treatment opportunity that may be available to them.⁵⁸

This document also says that patients will be contacted if there is a change in their result and their treatment may be affected. A patient contact number is also provided for those who might have questions.

There was a meeting of most of the Group on that day, October 3. Dr. Hunt of the Department of Health and Community Services and Mr. Tilley also attended. Dr. Williams recalled this as a meeting to try to decide what to do now that the matter was public knowledge. Dr. Williams acknowledged that at that point there was no contingency plan for the matter becoming public, nor had they planned what they would do when the results came back. Rather, they were going to see what the re-test results were first, and then develop a strategy.

⁵⁷ Exhibit P-0142.

⁵⁸ Exhibit P-0608.

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On October 4, 2005, there was a conference call with CEOs and VPs, Medical, of the other regional health authorities. The notes of Dr. Williams and Dr. Alteen support the conclusion that there was a discussion of the history of ER/PR testing, Peggy Deane's case (though Dr. Alteen noted that it occurred in May), and the general nature of ER/PR testing. The participants were told of the visits by Ms. Wegrynowski and Dr. Banerjee, though neither seems to have been named. They were told that: there were quality issues; that Eastern Health would be recommending that in future all ER/PR slides be read by two or three pathologists in St. John's; and that pathology assistants were needed, as were dedicated laboratory staff for immuno-histochemistry. Dr. Alteen noted, as a regional issue, the need to ensure collection and preparation (of specimens) followed a standard procedure across the province. He also noted that this should include the standardizing of formalin. Dr. Williams wrote: "Question of whether we should notify all patients who are being retested."⁵⁹

On October 4, Dr. Ken Jenkins distributed to various people within Western Health, including all physicians, questions and answers to help people answer questions from patients regarding ER/PR. Dr. Jenkins seems to have used the Frequently Asked Questions prepared for Eastern Health's website and added information relevant to Western Health. The reference to a new piece of technology having been introduced and the discovery of inconsistent results from the old system are the same in both. Patients of Western Health are to be told they will be contacted if there is a change to their test results and their treatment may be affected.

In St. John's, during this same time, Eastern Health was considering ways to communicate with physicians. Ms. Bonnell drafted a letter for Dr. Williams' signature. In it, physicians were told that there is evidence that taking tamoxifen "up to seven years post cancer may be beneficial to patients." That letter was posted on the Newfoundland and Labrador Medical Association (NLMA) website. A draft letter was also being prepared for Dr. Gardiner's signature. That letter included the

⁵⁹ Exhibit P-0609.

statement “some research indicates that Tamoxifen can benefit a patient up to ten years after diagnosis.”⁶⁰ It also stated that it was recommended that patients known to be ER/PR positive should be offered tamoxifen for five years. If it is contraindicated or not tolerated, then an aromatase inhibitor could be considered in post-menopausal patients. Dr. Gardiner’s letter was emailed to the Vice-Presidents, medical, of the other regional health authorities, who were asked to provide a copy to surgeons in their area.

On October 4, 2005, there were also indications that Eastern Health was beginning to make changes in response to the recommendations of Dr. Banerjee and Ms. Wegrynowski. In the operating rooms at Eastern Health, staff were reminded about the proper procedures for dealing with specimens removed from the patients. The same day, Mr. Gulliver informed Dr. Dan Fontaine that he and Dr. Cook were putting together a strategy to deal with the recommendations of Dr. Banerjee and Ms. Wegrynowski and in doing so they would address issues which Dr. Fontaine had raised in a letter to Mr. Gulliver. On October 13, 2005, Dr. Ejeckam was officially named to oversee the immunoperoxidase service at Eastern Health, including having direct supervision over the technologists involved in the service.

On October 5, 2005, the *Telegram* newspaper published a story by Ms. Deana Stokes-Sullivan. The headline was *Breast-cancer testing suspended*. Dr. Williams was the spokesperson for Eastern Health and is quoted extensively throughout the story. The interview addressed both the number of tests performed and the reason for the problem:

Most of the tests performed were positive, Williams said.

“We had about 73 per cent of tests that were positive, so we’re only retesting the... 27 per cent or so that were negative.”

And from the early results, Williams said, it appears only about 10 per cent of the overall tests performed over the past seven years show different results. ...

⁶⁰ Exhibit P-0620.

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The reason for the discrepancy in the breast tissue results isn't clear, but last year Eastern Health implemented a new fully automated system for detecting hormone receptors in breast tissue.

Williams said the older system was semi-automated and the testing involved multiple steps, including boiling or microwaving specimens to "tease out the antigen from the nucleus of the cell so the staining would be taken up by the antigen if there are receptors there."⁶¹

Ms. Stokes-Sullivan came away from the interview with the impression that Eastern Health was trying to say that the DAKO system was outdated, more difficult to use and more prone to errors. "I got the impression that it was because of the technology."⁶²

Another news story was causing some concern. On October 6, 2005, Mr. Peter Dawe told Mr. Tilley about a CBC online news story that was in error about the nature of the tests. It suggested that tests for the diagnosis of cancer were incorrect. Mr. Tilley brought the story to the attention of Ms. Bonnell, who responded: "Although I thought the CBC News Online piece is 'problematic' I don't think it is worth seeking a retraction. The more we drag this out, the worse it is for us." In the meantime, her colleague, Ms. Pennell, did not see it the same way. Ms. Pennell recalled that she called CBC to ask that the story be taken down. Ms. Stokes-Sullivan recalled that Ms. Pennell contacted her about the inaccurate CBC story because the story was attributed to the *Telegram*. In the end, likely through the efforts of Ms. Stokes-Sullivan in contacting the CBC, the error was removed by CBC.

By October 18, 2005, Ms. Predham was again working on the patient letter, that is, the letter to patients to tell them that their samples were being re-tested. The first such draft had been circulated some three months earlier. Ms. Predham sent her comments on the draft to the Group and pointed out some practical difficulties with the sending of the letter. She raised once again the problem of communication with patients from Saint-Pierre, the difficulty of determining to whom one communicates if the patient is in a personal care or nursing home,

⁶¹ Exhibit P-1662.

⁶² Transcript of testimony, Deana Stokes-Sullivan, October 30, 2008, p. 72.

whether the letter should be sent by registered mail, the potential for negative reaction from those contacted, and the possibility of sending a letter to those who are deceased and upsetting their relatives. She added: "Finally, I think we should be aware that we will not be able to notify everyone several on the list have moved and we have not other contact information." Ms. Predham advised the others (Dr. Williams, Ms. Bonnell, Ms. Pilgrim, and Dr. Laing) that she was going to send the draft to Mr. Boone: "I'm not sure how HIROC will feel about notifying people at this point in time and whether the media attention will make any difference." Mr. Boone, in fact, had already given her his comments on the idea of sending a letter to patients to tell them there would be a re-test. At the point when Ms. Predham was telling the others she was going to contact Mr. Boone, she had already spoken to him and was aware of his position. Mr. Boone provided a formal reply within the hour. He was opposed to sending "this letter at this time." He reasoned:⁶³

There are a significant number of people whose results will not be changed. Notifying these people may be seen as raising their hopes of treatment possibilities. In most cases, these expectations or hopes will not be satisfied. There is a possibility that we could be sued in a class action by those people who receive this proposed correspondence whose test results do not change. Otherwise these people would not have a cause of action, so sending the letter actually exposes us to a liability which does not now exist.

... I would think that most of the people who have tested negative would have enough information to consider whether they would like to be retested if they have not, and to enquire whether they have been retested.

Therefore, I do not see how the letter advances the health care of the affected patients and it increases our exposure to claims for damages. I would recommend against sending it.⁶⁴

On the afternoon of October 18, 2005,⁶⁵ after Ms. Predham's telephone conversation with Mr. Boone, a meeting was attended by Dr.

⁶³ Mr. Boone's reply was forwarded to others the next morning but by that time the decision had been made to abandon the idea of sending a letter.

⁶⁴ Exhibit P-2967.

⁶⁵ The original note of Dr. Williams is dated October 18, 2006. This is clearly an error. The note was made in 2005.

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Laing, Dr. Williams, Mr. Tilley, Ms. Predham, Ms. Bonnell, Dr. Cook and Ms. Pilgrim. At that meeting a decision was made to abandon the idea of writing to patients. A plan as to the future course of contact with patients was recorded in Dr. Williams' notes of that meeting to be the following:

1. There were going to be notices in the papers explaining the situation;
2. Patients who were to be re-tested would be called, as would those whose test results did not change;
3. Patients whose cases were examined by the Panel would be communicated with by a physician; and
4. Western and Central regional health authorities would phone their own patients.

Ms. Predham's version of how the decision was made to telephone patients was that it was a unilateral decision of Dr. Williams, who cut short any discussion about letters by pounding his fist on the table and saying that they would telephone the patients.

Dr. Williams' October 18 notes⁶⁶ referenced a plan for Western Health and Central Health to phone their own patients. While that is indeed what later happened for patients whose results were confirmed negative, Eastern Health in fact initially set out to phone all patients to let them know about the re-testing. As a result, Eastern Health staff spoke with family members of patients who, unbeknownst to Eastern Health, were deceased. Consequently, on October 25, 2005, Ms. Predham emailed Dr. Larry Alteen about having Central Health contact its own patients because local health authority staff would have better access to current information about patients.

On November 1, 2005, she emailed Western Health the script Eastern Health was using to advise its own patients about the re-testing process. Western Health subsequently attempted to notify its patients about the re-testing process. As of December 7, 2005, twelve patients had yet to be contacted. It was during the process of making these phone

⁶⁶ Exhibit P-1183.

calls that Western Health initially learned that a number of its re-testing patients were deceased.

By November 3, 2005, Ms. Hennessey was looking for information from Mr. Tilley: “where are we and when will all patients be contacted?” She added:

We need to ensure that the Minister can state all patients have been contacted when the House opens later this month.

Also, have you received the report from the Chief pathologist at the BC Cancer Institute and the Chief Technologist at Mount Sinai. If yes, can you give me a quick update to reflect in the Minister’s HOA note.⁶⁷

Mr. Tilley replied to the effect that he was then out of the Province and that a meeting had already been set for November 17 for the purpose of briefing the Minister before the opening of the House of Assembly. However, if Ms. Hennessey needed information she should contact Dr. Williams. Ms. Hennessey promptly did just that. In that email she told Dr. Williams that she was aware of the meeting on November 17 but that she had to complete the first draft of the briefing note by the next day and assured him that if, after the 17th, an update was required she would do that. As she had when she contacted Mr. Tilley, Ms. Hennessey wanted to know where Eastern Health was in contacting patients and “have you received the report from the BC pathologist and the Mount Sinai technologists. If yes, what is the general finding(s)?”⁶⁸

It was Ms. Predham who, on behalf of Dr. Williams, responded to Ms. Hennessey, providing her with information on where they were with 611 patients. Ms. Predham does not indicate what the 611 represents but does break down the number to indicate that some questions which had concerned Ms. Predham had been resolved, for example, the method of contacting the Saint-Pierre patients. She notes that there are eight in total and they will be contacted through Dr. Malluret. At the end of her email, Ms. Predham adds: “I understand that Dr. Williams has attempted to

⁶⁷ Exhibit P-3163.

⁶⁸ Exhibit P-1440.

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reach you to discuss the quality review. He will be following up with you on Monday.”⁶⁹

Ms. Hennessey prepared a Departmental Briefing Note dated November 7, 2005. However, there is no reference in this briefing note to the quality reviews. What, if any, discussion Ms. Hennessey and Dr. Williams had about the external reviewers’ reports is uncertain.

By November 17, 2005, in preparation for a meeting with the Minister, Eastern Health had prepared its own briefing note. The number of patients then said to be involved was 835 (898 specimens). The briefing note explained the role of the Panel, now said to comprise two surgeons, two medical oncologists, and two pathologists with clerical support from Quality Enhancement. At the end of the briefing note there is a reference to the deceased patients, said to number 158.

Arrangements will be made to notify family members once all results have been received.⁷⁰

Following the November 17 meeting with the Minister, Mr. Tilley advised others that the Minister’s communications director would be emailing questions to Ms. Bonnell and that the Department wanted answers by the end of the next day as the House of Assembly was about to open. Mr. Tilley added: “We will undoubtedly need everyone’s help in ensuring key messages are getting across.” When the questions arrived on November 18 they were forwarded to Ms. Predham. Ms. Predham took responsibility for preparing the first draft of the answers. A few minutes after receiving them, Ms. Predham was seeking the assistance of Mr. Gulliver to answer certain questions:

Has a review occurred to determine how this could have happened – how could there be inaccurate tests for a period of five years without being detected? Will there be disciplinary action taken?

Can the Minister ensure the public that this is not reflective of other unreliable methods of testing in the province? Is our health system safe?⁷¹

⁶⁹ Exhibit P-0098.

⁷⁰ Exhibit P-2985.

Later in the morning, Ms. Predham sent draft answers to some of the questions to Ms. Pennell, but at that point there were no answers to the questions which she had sent on to Mr. Gulliver. As it happened, Mr. Gulliver was on vacation, as was Dr. Cook. Ms. Predham turned to Mr. Dyer, who in turn sought the assistance of Dr. Fontaine.

At 1:48 p.m., Ms. Predham emailed the completed draft answers to Ms. Pennell, asking Ms. Pennell to call her. The draft included Dr. Fontaine's comments, which were highlighted in italics:

ER/PR Questions

- ...
- Why weren't patients immediately notified that the samples were being retested and were forced to find out through the media? Would the minister not acknowledge that this has created anxiety for all patients who had been tested in the last number of years?

The decision whether or not to notify patients about the retesting of samples was very difficult to make and caused much debate within Eastern Health and HCS. Eastern Health has made the commitment to candid and timely disclosure to every patient any knowledge of an adverse event. However, a critical component of this situation was that this is still an ongoing investigation; until all the results from retesting are obtained; it is impossible to determine the scope and cause of the problem or the impact on the individuals.

It was always the intent to inform each individual and to disclose the information regarding the problem publicly when the retesting results were done. There was no ill intent in the delay, but it was felt that not being able to give the results or an accurate timeline as to when the results would be obtained would cause even greater anxiety in those affected.

- ...
- Has a review occurred to determine how this could have happened - how could there be inaccurate tests for a period of five years without being detected? Will there be disciplinary action taken?

This is still an ongoing investigation; until all the results from retesting are obtained; it is impossible to determine the exact details of the scope and cause

⁷¹ Exhibit P-2989.

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of the problem. Three reviews have taken place; of our current testing procedure, our pathology services and our technical services. Recommendations have been made and are being acted upon which will immediately ensure the quality and reproducibility of results.

These are details supplied by the lab:

It was found there were problems with interpretation and quality of specimens used for interpretation. There was no Q.A. program in place being monitored by one individual.

Too many individuals were involved without delegated responsibility and required individuals may be unfamiliar with standards required for interpretation.

Actions:

Implementation of a subspecialty sign out, so only a few individuals will be responsible for overseeing the performance and interpretation and will also allow for individuals to maintain expertise in subspecialty area.

CME will be provided for interpretation.

Labs will undergo accreditation

- ...
- Can the Minister ensure the public that this is not reflective of other unreliable methods of testing in the province. Is our health system safe?

All laboratories across the province [sic] This incident has raised the awareness within Eastern Health of the need of focused resources for the Immunohistochemistry service for dedicated subspecialty sign out of pathology cases. Also dedicated technologists to be assigned to performance of highly specialized tests. We are now also subscribing to external proficiency testing.⁷²

At 4:07 p.m. Ms. Pennell sent to Ms. Predham, Dr. Williams, and Mr. Tilley, for review and return to Strategic Communications by Monday, a draft of the responses to the questions. This draft did not contain the information supplied by Dr. Fontaine. The question remains: why was the first real information about what gave rise to the ER/PR problem not shared with the Minister and who decided that it should not be? Neither Ms. Pennell nor Ms. Bonnell could say who had removed the information supplied by Dr. Fontaine. Ms. Predham's testimony indicated she believed that Mr. Tilley had made the decision. In any event, within Eastern Health the decision was made to remove from the answers going to the Minister specific information relevant to the cause of the ER/PR problem.

⁷² Exhibit P-1506.

On Sunday, November 20, Mr. Tilley, using an editing feature of his computer, replied with his suggested changes. The program Mr. Tilley used to make the changes has a tracking feature that reveals what the draft answers were before Mr. Tilley made his changes.

The changes Mr. Tilley made were extensive, and reflected his take on the problem. He emphasized the lack of national standards for the test and referred to literature which suggested “that these tests have limitations.” He referred to the patient safety movement perspective when he said:

With respect to disciplinary action, to date there is no evidence of a deliberate break down of procedures on any person’s part. Furthermore the current focus of the Canadian patient safety movement is to create work environments where mistakes are acknowledged to promote disclosure and follow up as quickly as possible. To that end disciplinary action is discouraged.⁷³

Later in his revision, Mr. Tilley added, in response to the question, “Can the Minister ensure the public that this is not reflective of other unreliable methods of testing in the province? Is our health system safe?”:

Eastern Health responds successfully to the needs of thousands of patients in any one year. Furthermore, it has quality monitoring programs in place and has highly qualified professional on staff. While regrettable, the fact that this situation was identified in the first place is reflective of the importance of quality in the organization. I am confident that this is not reflective of the services provided.⁷⁴

Mr. Tilley was, in his revisions, emphasizing the “key messages” that were important for him.

The purpose of the exercise was to enable the Minister to answer questions about the ER/PR issue. As one follows the information from Ms. Predham to Ms. Pennell (and Ms. Bonnell) to Mr. Tilley, there is a pattern. Of the three, Ms. Predham’s answers contain the most precise information including “the details supplied by the lab.” The responses in the Pennell/Bonnell version are vaguer and contain phrases about

⁷³ Exhibit P-0473. p. 44.

⁷⁴ Exhibit P-0473, p. 44.

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Eastern Health's priorities and taking action. They certainly bear the hallmarks of a communications department. Mr. Tilley's version reflects his interest in the patient safety movement and the concept of a "blameless culture."

The revised questions and answers were sent on November 21, 2005, by Ms. Pennell to Ms. Mundon. The next briefing note prepared for the Minister within the Department of Health and Community Services, dated December 5, 2005, for the Minister was described as a Question and Answer briefing note. It does not contain the information in the briefing note prepared by Eastern Health for the meeting with the Minister on November 17, nor does it contain the information in the "Answers" prepared by Eastern Health between November 17 and November 21.

During the fall of 2005 and winter of 2006, Eastern Health concentrated on dealing with the return of the re-test results and the communications with patients. There continued to be media interest in the story, and both Government and Eastern Health in 2006 received Access to Information and Protection of Privacy requests for documents relating to the ER/PR matter.

February - August 2006

On February 23, 2006, another Question and Answer briefing note was prepared for the Minister. Included in the briefing note was a statement to the effect that the recommendations of the external consultants had been implemented and the consultants would be returning to Eastern Health in April to review what had been done. In this briefing note, the number of re-tests is said to be 939 "tissue samples."

On March 17, Dr. Alteen noted that in a telephone call Ms. Predham once again explained the course of action that would be taken after patients were paneled. Eastern Health agreed to send to Central Health the script Eastern Health had for calls to patients whose results were unchanged because Central Health would do the calling for patients in its jurisdiction who did not have a change in result. Dr.

Alteen's notes add: "Deceased will be reviewed and panel deceased converted patients." Ms. Predham sent the Eastern Health script for speaking with confirmed negative patients to Central Health on March 22, 2006. She advised that they were not leaving messages; if they could not speak to the patient they would call back later. Part of the script read, "We are pleased to tell you that we have your results back and there is no change from what they were originally."

During the spring and summer of 2006, Dr. Williams, Dr. Denic, Dr. Cook, Dr. Laing, Heather Predham, Ms. Nancy Parsons, and to a lesser extent Ms. Patricia Pilgrim and Ms. Pam Elliott became involved in efforts to address the circumstances of those patients they commonly referred to as Ductal Carcinoma In Situ (DCIS) and retro-converters. Those efforts and the communications related to them are discussed separately in this report.

The June 7, 2006, minutes of the meeting of the Executive Management of Eastern Health include the subject of briefing notes prepared within that organization. Ms. Louise Jones, Chief Operating Officer, Adult Acute Care, argued that there should be guidelines for briefing notes. The concern was that when briefing notes were forwarded to those outside Eastern Health it gave rise to "serious confidentiality issues." The minutes add:

It was also noted that Briefing Notes to the Minister that go to Cabinet are protected. However, briefing notes sent directly to Minister are not. All documents forwarded to the department must have "confidential" watermark. Any document forwarded externally must go through the Director level first prior to release and in some cases, where necessary through the Executive.⁷⁵

On July 5, 2006, Dr. McCarthy and Dr. Carter wrote to Dr. Williams about creating a breast disease site group at Eastern Health. The letter says: "As you recall, the impetus for this group came from your office as a result of multiple meetings concerning ER and PR laboratory testing and the care of patients with breast cancer in this Province."⁷⁶ The

⁷⁵ Exhibit P-0777, p. 2.

⁷⁶ Exhibit P-1140.

authors attached a proposal for the development and staffing of the breast disease site group.

On July 31, 2006, Ms. Predham, in response to a request from the Department of Health and Community Services, completed an update in which she says that the total number of patients sent for re-testing was 939. The majority of the results had been returned and reviewed, and the patients informed. The exceptions discussed include the patients who were identified as wrongly diagnosed because of the review of DCIS patients and the retro-converters, who were said to be four women who would be met with in the near future. Exceptions also included the deceased, for whom the recommendations of an ethics panel would be followed respecting disclosure to the families of those patients. Ms. Predham also described two legal actions that had been started, one of which sought certification of a class action.

Ms. Predham's update was forwarded to the Department, where Mr. John Abbott, the Deputy Minister, and Mr. Tom Osborne, the Minister, received copies. The Department sent the update to Mr. Gary Cake of Cabinet Secretariat.

During late July 2006, there was media activity about the ER/PR issue and the class action law suit, including an interview with Ms. Myrtle Lewis and the solicitor for the class action group, Mr. Ches Crosbie.

On August 2, 2006, Ms. Bonnell reached out to Ms. Jo-Anne Polak, Senior Vice-President of Hill & Knowlton Canada, for advice. It is clear Ms. Bonnell was concerned about the communications aspects of the matter. She described herself as "sitting on top of an angry volcano that keeps erupting" and noted that "no crisis plan exists." Ms. Polak responded, indicating that she was prepared to speak to Ms. Bonnell.

By August 3, 2006, the CBC program the *Current* wanted to do a story and was looking for someone from Eastern Health to comment. No one then available within Eastern Health was prepared to appear on the program. In the end, CBC broadcast a written statement from Mr. Tilley.

Ms. Bonnell also provided the producer of the program with some “background” information. That information included the following statement: “Last summer, after introducing a new technology that tests for ER/PR in our laboratory at the Health Sciences Centre, Eastern Health became aware of inconsistencies in test results.” She added:

In the vast majority of cases reviewed thus far, there is no change in ER/PR status that requires a change in the treatment plans adopted for patients.

Once we have completed the review of all the individual cases we will be in a better position to assess the reasons for the inconsistencies in the test results.

Although we are aware that experiences such as the ones that prompted our review have occurred in other places, we are unaware of another centre that has conducted a retrospective review such as ours.⁷⁷

Mr. Tilley’s statement provided to the *Current* included references to the discovery of the problem and the results on the re-tests. There was very little detail:

Eastern Health originally began a review of all ER/PR receptor tests conducted by our laboratory since 1997 when we discovered inconsistencies in a small number of results.

Our first priority was and continues to be to our patients.

More than 900 test samples were sent to Mount Sinai Laboratory. Collecting, sending, retesting and reviewing all these test samples has been an extensive process, but most tests have been reviewed and most patients have been notified. In the majority of cases the patient's treatment was confirmed appropriate.

As part of the review we have identified a small number of cases that require further follow-up. We are in the process of reviewing and addressing each of these cases individually.

Eastern Health is committed to disclosure and our clinical team members have communicated individually with all patients impacted by this review. However, patient confidentiality is an important principle in health care, not

⁷⁷ Exhibit P-1159, p. 2.

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only in this province but across the country, so we do not discuss the details of individual cases publicly.

As to the statements of claim filed against the organization, every individual has the right to take whatever action they deem appropriate and we must allow the legal system to address the legal issues.

As a health care provider, we will stay focused on ensuring that our patients have every treatment opportunity that may be available to them and on addressing the systems issues that arise.

Eastern Health would like to assure the public that we take these matters seriously, that we have a team of clinical and administrative people working on this issue, and that we are dedicated to improving the system, learning from our experiences and ensuring quality care.⁷⁸

This was the first public statement by Mr. Tilley, the CEO of Eastern Health, on the subject of the ER/PR problem.

On August 3, 2006, Ms. Bonnell sent ideas to Ms. Predham for her “perspective/comments/additional thoughts.” The email provides reasons for disclosure of error and addresses the question of what this does to “faith in the system.”

Around the same time, there was another story on the CBC website which stated that 10 to 20% of the persons re-tested were misdiagnosed. The story focused on DCIS patients. Ms. Predham, in investigating this, discovered that the DCIS issue was raised in a statement of claim filed on July 7, 2006, by the law firm of Mr. Ches Crosbie. Since the DCIS patients who had been misdiagnosed had not been informed until July 12, she wondered how Mr. Crosbie knew about it before July 12. This seemed to feed the idea that there was a mole in either Eastern Health or the government from whom Mr. Crosbie was receiving information. The adverse publicity arising from the disclosures to certain DCIS patients was also causing concern about the notification for the retro-converters. Ms. Predham raised it with Ms. Pilgrim, who in turn raised it with Dr. Williams.

⁷⁸ Exhibit P-0102.

On March 14, 2006, Mr. Tom Osborne was appointed Minister of Health and Community Services, replacing Mr. Ottenheimer. Mr. Hynes remained with the new Minister, although in a slightly different capacity. He recalled trying to arrange a briefing about ER/PR for the Minister in early August 2006. In fact no briefing occurred until November 23, 2006, though the Minister was pressing for information. Mr. Osborne was asking about the root cause of the ER/PR problem and, as Mr. Hynes put it, as senior policy advisor, he had no answer to give him. Mr. Hynes might have been in a position to provide an answer had Eastern Health, in November 2005, not deleted the details provided by Dr. Fontaine from the answers to questions being sent to Government.

In August, 2006, Mr. Mark Quinn of CBC radio was continuing to follow the story. Ms. Leona Barrington, who by then had replaced Ms. Pennell in Strategic Communications, was having discussions with Mr. Quinn about providing him with a briefing with Eastern Health's "key players." Ms. Bonnell was reluctant to arrange it during that week because they did not have a spokesperson to address the issue.

On August 7, 2006, Ms. Bonnell and Ms. Lynn Barter, Communications Director with the NLMA, again discussed the use of the NLMA in communicating with general practitioners. Both feared that the messages in the public were mixed and that general practitioners were receiving calls they were not equipped to answer. In the meantime, Dr. McCarthy had advised Ms. Sharon Smith, Director of the Cancer Care Program, that the Cancer Centre was not receiving any additional calls as a result of the media coverage during that period.

On August 10, 2006, Ms. Predham emailed Ms. Elliott a draft briefing note demonstrating concerns with what information could be provided to Government, or concerns relating to creating a record of the information Eastern Health was providing to Government. Ms. Predham states "Also, I didn't include the [information] about the reviews ... I think we can tell them that, but I don't want to write it down..."⁷⁹

⁷⁹ Exhibit P-3039.

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Ms. Marilyn McCormack, then a Cabinet Officer (Special Projects), in Cabinet Secretariat, was not regularly assigned to the Department of Health and Community Services, but in August 2006 she was covering that department for someone who was on holiday. Her position required her to review cabinet submissions and analyze any recommendations, paying particular attention to considerations that might be wider than those of any one department. On July 31, 2006, Mr. Cake had asked Mr. Abbott for a briefing note on an issue raised in the *Independent* about a class action lawsuit launched by breast cancer patients. In that communication, which was copied to Ms. McCormack, Mr. Cake noted that the last briefing note in the Cabinet Secretariat system was October 5, 2005. Mr. Cake's intent was to send the updated information on to the Premier's Office. The Department had responded by sending him a copy of a briefing note prepared by Ms. Predham on July 31, 2006. It was not in the proper form and Ms. McCormack was therefore asked to follow up on the briefing note and see that it was put in the proper form.

Ms. McCormack consulted with Ms. Hennessey. Ms. Hennessey was traveling at the time, so it was agreed that Ms. McCormack would reformat the July 31 note and then send it to Ms. Hennessey, who would be able to answer some of Ms. McCormack's questions. Ms. McCormack had not been involved in the ER/PR issue before and was not aware of the background. She had a number of questions. She wanted more detail about the role of the Panel. Ms. Hennessey's answers demonstrated an understanding of the process established at Eastern Health for the re-test results. She was not, however, able to answer Ms. McCormack's questions about the DCIS patients still under review and suggested that Ms. McCormack deal directly with Ms. Predham on the issue. Ms. McCormack contacted Ms. Predham as Ms. Hennessey had suggested. On August 17, 2006, Ms. McCormack sent the revised briefing note to Ms. Hennessey and later that day to Mr. Abbott, whom she informed that the note would probably go to the Premier's office that day or the next.

Before completing the final copy of the briefing note, Ms. McCormack went back to Ms. Predham with a question regarding how many women were most affected by the change in status of the ER/PR

receptor tests. Ms. Predham said 22, and that figure was included in the briefing note forwarded to the Premier's office on August 18.

It is difficult to reconstruct from what sources Ms. Predham determined the number to be 22. Through Eastern Health's counsel, she advised the Commission that included in the number were the 13 patients who had not been offered tamoxifen originally because of the report of a ER/PR negative test result, but who, before the retrospective re-testing, had a recurrence or metastases and had been placed on tamoxifen as a result of testing at that time. As for the other nine, she included those because of comments she had heard during the Panel meetings as individual cases were being discussed. This somewhat casually determined number was to influence others' understanding as to the extent of the problem. One such person was Premier Williams, who read that with hundreds of people being re-tested and slightly over 100 having treatment recommendations, 22 were impacted. While not understating the seriousness of the impact for those 22, the use of that figure in the larger context diminished the magnitude of the problem for the Premier and his immediate staff.

The penultimate draft of the August 18, 2006, briefing note had in fact referred to those 22 patients having been "greatly impacted." The word "greatly" was, unfortunately, at the instigation of Ms. Hennessey, removed from the final version, based on her professed uncertainty as to whether in the circumstances such a modifier was appropriate. One effect of its omission was to dilute the message that while some individuals were very seriously negatively impacted, many others were also negatively affected - albeit to a lesser extent.

Ms. Rosalind Jardine was one the 22 patients identified as having been the most impacted.

Rosalind Jardine

It wasn't handled from a patient's perspective

Ms. Jardine is a resident of Conception Bay South. She is the spouse of a physician. She was diagnosed with breast cancer in October

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1999. Dr. Laing is her medical oncologist and Dr. Ganguly is her radiation oncologist. On October 27, 1999, Dr. Denic entered the result of her hormone receptor test on her chart. She was negative for ER and 25-30% positive for PR. In a Progress Note to her chart dated December 3, 1999, Dr. Ganguly wrote: "ER/PR status - ER negative. PR positive 25-30% of tumour cells, which according to old standard will be called equivocal or border line positive....In terms of tamoxifen, I am not sure one way or the other, however seeing that the tumour has probably progressed while on HRT, it may not be unreasonable to prescribe tamoxifen to this lady following completion of her chemotherapy."⁸⁰ Ms. Jardine was not aware that this was Dr. Ganguly's view at the time. On March 7, 2000, she was seen by Dr. Laing. The Progress Note for that date states, "Her tumour was ER negative and PR was only 25-30%. Therefore she is not a candidate for tamoxifen... I do not believe the benefit to her in this case would outweigh the risks."⁸¹ Ms. Jardine understood that Dr. Laing consulted Dr. Ganguly on this. Ms. Jardine was not prescribed tamoxifen. She underwent chemotherapy and radiation.

On November 16, 2004, Ms. Jardine's chart noted that she was doing well. She was then five years post-diagnosis. The next Progress Note almost a year later, on October 13, 2005, painted a much bleaker picture. Her cancer had spread to her bowel and bones. The Progress Note for that date referred to a repeat ER/PR test that was pending. Dr. Laing writes, "This lady's initial tumour was estrogen receptor negative and had progesterone receptor staining in 25% which in those days was reported as being negative as well. Her repeat testing has not been done and I spoke with Dr. Cook today who is going to send her slides as an urgent referral to Mount Sinai."⁸² In fact, Ms. Jardine had become ill a couple of weeks earlier, which resulted in her being hospitalized for approximately ten days and undergoing surgery on September 22, 2005. Dr. Kwan was her surgeon. Ms. Jardine was not informed of the ER/PR re-testing while in hospital. In fact, the only information she had about the issue prior to her discussion with Dr. Laing on October 13, 2005, was what she had heard in the media. When Dr. Laing discussed the ER/PR

⁸⁰ Exhibit C-0075.

⁸¹ Exhibit C-0077.

⁸² Exhibit C-0080.

issue with Ms. Jardine on October 13, 2005, she told her that this was an enormous problem. On October 2, 2005, Dr. Laing is quoted in the *Independent* story as having stated that, “it is not a huge thing.”

Ms. Jardine’s sample was sent as a consult to Mount Sinai. Dr. Mullen reported the result on October 27, 2005, exactly six years after her first hormone receptor test. Ms. Jardine was ER 50% positive, PR 20% positive. The next day, Dr. Cook entered the result on her chart and Dr. Laing met with Ms. Jardine and broke the news. She was started on anti-hormonal therapy. Dr. Laing was very apologetic to Ms. Jardine. She understood from Dr. Laing that there were many things that could have contributed to the changed result but there was nothing definite.

Ms. Jardine’s case was reviewed by the Panel in December, 2005. On December 18, 2005, Dr. Laing wrote a letter to herself and copied it to Dr. Kwan, Dr. Felix and Ms. Jardine’s family physician summarizing the recommendation of the Panel. Ms. Jardine’s re-test results are referenced in the letter. “We understand that this lady has been informed of the above results and treated appropriately. Therefore, there is no recommendation from the panel at this time.”⁸³ Ms. Jardine was unaware that the Panel had reviewed her case or of the existence of this letter until preparing for the Inquiry process in 2008. It is difficult to see what benefit there was to the Panel process in her case given that her treatment had been changed weeks before.

Even though Ms. Jardine’s treatment clearly changed as a result of the re-testing process, Ms. Jardine was not counted amongst the 117 number that was publicly released by Eastern Health at the Media Technical Briefing on December 11, 2006 as the number of patients who had required treatment changes. Eastern Health representatives who attended the Media Technical Briefing, which included Dr. Laing, had contended this was the only important number. That number, however, was not accurate. There were many patients such as Ms. Jardine who, in fact, received treatment changes prior to being reviewed by the Panel and were excluded from Eastern Health’s calculations.

⁸³ Exhibit C-0082.

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Ms. Jardine considers herself to be more fortunate than most patients in terms of how she was communicated with on the ER/PR issue. She was advised personally by her oncologist that her sample was being sent for re-testing and her sample was given priority as a consult. She also learned promptly of the change in her results and was started on anti-hormonal therapy immediately upon the re-test results being received by Eastern Health. Overall, however, Ms Jardine feels that Eastern Health handled the communication process very poorly. Eastern Health's handling of the ER/PR issue has created an erosion of her trust in the health care system. She is now fearful when she goes for a test and is constantly second guessing whether the test is, in fact, being read correctly. In her words, the issue was not handled from a patient's perspective. She was shocked to first hear of the issue through the news media. She felt the proper protocol would have been for patients to be informed of this by their individual physicians.

Ms. Jardine's case is particularly tragic in that she is one of the patients who might not have developed metastatic disease had she been offered the correct treatment originally. Ultimately, it is her hope that the Inquiry process will lead to a more transparent system

whereby everybody affected with a disease such as cancer would be privy and would be a part of that communication system openly, because that's so important. That gives ... us a power that we still have input and somewhat, though very limited, control on this disease process that's happening... when you're not informed and it's happening kind of outside of you, you feel so insignificant. You feel that your life doesn't count at all.⁸⁴

October - December 2006

By October 20, 2006, the executive committee of the Department was recording some frustration because some patients still had not been notified at all about re-testing of ER/PR samples.

On October 26, 2006, Ms. Predham provided information to others about the way the Panel had chosen to deal with one of four retro-

⁸⁴ Transcript of testimony of Rosalind. Jardine, March 24, 2008, p. 91.

converters. The patient was paneled on September 8, 2006. The original idea had been to arrange a meeting with her and the clinical chiefs but that notion was questioned because of the media coverage after the DCIS meetings. When it was discovered that one earlier retro-converter had been informed by means of a panel letter to the patient's physician, that approach was also chosen for the woman paneled on September 8, 2006. The letter had gone to Dr. Chaudhary Ahmad, an oncologist, who had sent it to the patient's family physician, who in turn gave the letter to the patient. The patient then called looking for the contact information for the class action group. Ms. Predham was anticipating that there would now be a call for the re-testing of all ER/PR results. She added: "but there is a documented false positive rate with this test and five out of 962 falls well within that range. Of course, we can revisit this decision."

In November 2006 Mr. Tilley and Ms. Dawe attended a Canadian Patient Safety Institute (CPSI) conference held in Halifax. Mr. Tilley gave a presentation on "Going Public" in which he talked about the principles involved in disclosure and what had happened at Eastern Health. Mr. Tilley spoke about it being a systems issue, not a typical medical error. Nothing that was said by Mr. Tilley in the presentation caused Ms. Dawe to question her belief that the problem was caused by a change in the equipment used by Eastern Health.

The media was still interested in the story. On November 22, 2006, Ms. Chris O'Neill-Yates, of CBC, emailed Ms. Mundon complaining that she could get no response from Eastern Health. She was looking for a rate of error.

On November 23, 2006, there was a meeting scheduled on short notice with Mr. Osborne. Ms. Predham was preparing the data for the meeting and Dr. Oscar Howell asked Ms. Predham if they were "able to scrub data sheet on contacts/conversions before meeting with minister today?" Ms. Predham replied with a summary of the numbers and asked if it was okay as she was not sure what scrub means. The data she provided was:

Total retested: 939.
Confirmed negative: 341

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These were the ones that had no change in the values and could be determined as negative without further review. There were others determined through the paneling process (see below)

Patients paneled: 422

Converted with no treatment recommendations: 208

- No recommendation: low risk: 60
- No recommendation: previously treated with Tamoxifen or another aromatase [aromatase] inhibitor (148)
 - **This group includes a group identified as being potentially impacted:** those not placed on Tamoxifen for their original disease, but for subsequent metastatic disease (13)

Converted with treatment recommendations: 109

- This group includes patients whose results have not changed significantly, but the clinical definition of positive and negative has changed since the time of diagnosis. (13)
- **This group includes a group identified as being potentially impacted:** those impacted by the delay in receiving Tamoxifen: i.e. their disease has progressed (9)

Confirmed negative: 28

- As noted above, these patients' original results were considered to be negative by the treating clinician and treated appropriately. There was a slight change in the patient's ER/PR status but review by the panel confirmed the ER/PR status as still being negative. No action other than notification was required.

Confirmed positive: 12

- These patients' original results were considered to be positive by the treating clinician and treated appropriately. There was a slight change in the patient's ER/PR status but review by the panel confirmed the ER/PR status as still being positive. No action other than notification is required.

DCIS

- Confirmed DCIS: 52
- Follow-up required: 4

Required assessment prior to recommendation: 5

- The panel could not make a recommendation for these patients without seeing the patient.

Retro Convertors: 4

Patients who are deceased (176):

- 101 were retested and results received.
- There have been 2 retested upon request. The remaining 63 will not be retested unless the families approach us.⁸⁵

About an hour later, Ms. Predham sent to Ms. Elliott and Ms. Debbie Parsons a revised version of the information:

Total cases reviewed 1997-August 2005: 2760 cases

Total retested: 939.

Results obtained and reviewed: 763

No change in results and subsequently no change in treatment: 433

Confirmed negative: 341

Confirmed negative from panel: 28

Confirmed positive: 12

DCIS: 52

No change in results; requires change in treatment as definition of negative has changed: 13

Change in results but does not require treatment change: 213

No recommendation because they are low risk: 60

No recommendation because they are previously treated with Tamoxifen or another aromatase [aromatase] inhibitor: 148

This group includes a group identified as being potentially impacted: those not placed on Tamoxifen for their original disease, but for subsequent metastatic disease (13)

No treatment because they required assessment prior to recommendation: 5

Change in results and requires treatment change: 104

Recommended for treatment with Tamoxifen or aromatase [aromatase] inhibitor: 96

Originally diagnosis revised: 4

Originally had a degree of ER positivity but on retesting was negative: 4

Patients who are deceased (176):

101 were retested and results received.

⁸⁵ Exhibit P-3053.

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There have been 2 retested upon request. The remaining 73 will not be retested unless the families approach us.⁸⁶

The two versions contain essentially the same numbers. There is, however, no reference in the second version, to the group of nine who were earlier identified as potentially impacted by the delay in receiving tamoxifen because their disease had progressed. Further, the second version uses the word “change” rather than “converted,” and omits the information that four DCIS patients require follow up.

The second version was given to the Minister during the meeting. Mr. Osborne remembered the meeting of November 23, 2006, which was held in the Clerk’s boardroom, just outside the House of Assembly. The meeting was attended by Mr. Tilley, Dr. Howell, Dr. Laing, and Dr. Nebojsa Denic from Eastern Health. Mr. Abbott, Ms. Mundon, and Mr. Hynes were there from the Department. Mr. Hynes recalled that Ms. Bonnell of Eastern Health also attended. All those in attendance knew that Eastern Health was planning to conduct a media technical briefing within the next few weeks.

Mr. Osborne was in the habit of writing notes on the margins of briefing notes. He did so on November 23 and this assisted him in remembering the specifics of the conversation on that day. The meeting included a heated discussion that he probably would have remembered in any event. He recalled going through the numbers quickly until they got to the number of patients who required treatment change, which Eastern Health focused on. That number was 104. Mr. Osborne, however, insisted that 13 be added to that number. There are two references to 13 in the data. Ms. Bonnell said in an email dated December 9, 2006, that the 13 added were patients who had no change in results but whose treatment was changed because of a change in the definition of what is positive. Mr. Abbott had the same recollection.

The discussion then turned to the deceased, which is when, as Mr. Osborne put it, the “meeting went off the rails.” Eastern Health advised

⁸⁶ Exhibit P-3054, p. 2.

the Minister that 103 results⁸⁷ of deceased patients had been received but the other 73 would not be re-tested unless families asked Eastern Health to have the re-testing done. Up to that point, Mr. Osborne had thought that all 939 patients would be re-tested.⁸⁸ He understood and accepted that an ethics consult had recommended that the results for a deceased patient would not be released unless the patient's family requested them. Mr. Hynes asked why the numbers for the deceased were not available. Mr. Osborne recalled the response was that their time and resources were better spent on the living. Mr. Osborne's note records the comment "concerned with the living" which he attributed to Dr. Laing. He recalled that it was Mr. Hynes who replied to the effect that Eastern Health would have to come up with a better answer during the media briefing. Mr. Osborne asked if the re-test results for the remaining 73 deceased patients would be available for the press briefing. He was told that they would not be.

It was Mr. Osborne's view that if a true picture were to be presented to the public, the individuals who would have had a change in treatment, or could have benefited or potentially benefited had they not died, would have to be factored into the overall numbers. Mr. Osborne had recorded, "How many deceased would have had a change in treatment? Don't know." Mr. Hynes said that during the meeting of November 23 he recalled a conversation he and the Minister had had with Dr. Laing in November 2005 in which she had said that there was no doubt that people would have died because they had not received tamoxifen.

Mr. Osborne's notes also indicate that the Canadian Cancer Society was to receive a pre-briefing before the media technical briefing to be held the next week. Mr. Hynes said that Mr. Abbott was pushing for a briefing for Mr. Dawe, and he had the sense that Eastern Health was

⁸⁷ 101 deceased were re-tested originally and two deceased were re-tested upon request of their families.

⁸⁸ The figures provided to the Department over the months generally listed "total retested." When the data included reference to the deceased it became clear that just over 70 of the deceased had not, in fact, been retested. However, up to this point, no one seems to have questioned the presentation of the data.

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resisting the idea, and that the relationship between Eastern Health and Mr. Dawe had soured.

Mr. Osborne was told during the meeting that three to four percent was within the margin of error but he could not recall what the three to four percent represented. Mr. Hynes recorded in his notes that it was three percent of 2800 cases which was said to be within the margin of error for the test. He recalled that it was Ms. Bonnell who noted that the 109 (this number should be 104 or 117) patients who had had changes in treatment were well within the margin of error of three percent. Mr. Hynes understood he was being told that a three percent error rate was considered acceptable for this test. He took this to be good news.

Mr. Hynes also recalled that the defence to the class action was going to be based upon the probability of the test. Mr. Hynes understood that the defence would be that the system was unreliable because it was multi-stepped with a lot of manual manipulation, so there was a certain amount of inherent error, and the error rate in this case was within an acceptable range.

Mr. Osborne also questioned the origin of the problem: had it been determined it was a systems error? The response from Eastern Health was that they had confidence in their professionals and stood behind them. Eastern Health also told the Minister that at the media briefing there would be no comment of this nature “because that’s the question that’s before the Courts and it’s a question for the Courts to decide.” Mr. Osborne understood that Eastern Health did not believe the laboratory staff had made mistakes but they would not be talking about whether it was a systems or a laboratory error. This information, coupled with the statement that the defence in the class action would be that the system was unreliable, would have indicated to the Minister that nothing more than the anticipated variation in results for this test had occurred. Mr. Osborne believed that the only limitation on comment for the media briefing related to the cause of the changes in results. He understood that otherwise the information he had seen would be released to the media. Like Mr. Osborne, Mr. Hynes believed that Eastern Health was not going to speak about causation but that the numbers and everything

else that had been provided on November 23, 2006, would be shared with the media at the briefing.

Mr. Osborne himself later noted the contrast between this position and Dr. Laing having been quoted in a story in the *Independent* on December 15, 2006, as saying that it was a systems error. However, he did not make that observation in December 2006. Mr. Osborne understood that the systems error had to do with the DAKO system and that the Ventana Benchmark was a better machine.

Following receipt of the ER/PR case analysis document provided by Eastern Health on November 23, 2006, there was a Question and Answer briefing note prepared. Interestingly, this note begins with a statement about mistakes in a breast cancer screening test, rather than a hormone receptor test. This was the error in description of the problem which Eastern Health had complained bitterly about when it occurred in media coverage.

On November 27, 2006, Ms. Mundon followed up with Ms. Bonnell regarding the briefing for Mr. Dawe. Ms. Bonnell replied that the media briefings would be on December 11. She adds: “we will try to make time for Peter on that day but I’m not sure if we will be able to fit him in. He won’t be getting the advance ‘good-will’ presentation I offered him last week ...you thro[w] someone an olive branch and they whip you to death with it fool me once”⁸⁹

In the meantime, there were communications problems between Eastern Health and the Department as well. On December 4, 2006, Mr. Abbott, Mr. Tilley, Ms. Bonnell, and Ms. Mundon met to resolve those issues. Mr. Abbott was concerned about whether the Department was being kept apprised of events at Eastern Health. The meeting specifically addressed the plans for the ER/PR media briefing, which was coming up shortly. Mr. Abbott wanted to know what they planned to say about the deceased patients. He knew that Eastern Health would not discuss error rates. While Mr. Abbott generally felt the Department should provide assistance to the Minister as needed and had no role vis-à-vis the regional

⁸⁹ Exhibit P-0181.

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health authorities, on this occasion he clearly took on just such an oversight role.

On December 6, 2006, just days before the media briefing, the subject of communications was under consideration at the Executive Management Committee meeting at Eastern Health. Mr. Tilley, Dr. Howell, Ms. Pilgrim, and Ms. Jones were in attendance. Ms. Bonnell was not. The minutes include the following:

ER/PR - Estrogen and Progesterone [Progesterone] Testing Review - Media Briefing

Dr. Howell advised that next week there will be a briefing to the Media on ER/PR. Susan Bonnell is involved in preparing the media briefing.

Executive discussed the pros and cons of going back to the media on this issue including the limitations in light of the fact that the findings in the review are protected under the Evidence Act. However, Executive was supportive of moving forward with the media briefing, including the technical briefing to cover areas such as chronology of events, understanding of the principles and practices of disclosure, understanding the ER/PR test.

The organization plans to resume testing in our Laboratory in early 2007.

On a related note Dr. Howell advised that:

- Dr. K. Laing has agreed to stay on as Clinical Chief
- Campaign by Oncologists to resign effective January 1, 2007 is ongoing
- Gyne. Oncology were threatened to withdraw service in mid November. Currently two physicians on maternity leave - consequently leaving only one physician who is requesting additional remuneration for on call.⁹⁰

On December 7, 2006, Ms. Bonnell sent to several Eastern Health personnel Ms. Predham's calculation of the error rate (11.97%). Ms. Bonnell underscored that this was not to be shared with the media. The plan was to hold two separate briefings, one for three CBC reporters and the other for reporters from the *Telegram*, the *Independent*, NTV and VOXM. They were to make medical personnel available for interviews on the afternoon of December 11 and offer a visit to the laboratory to see the

⁹⁰ Exhibit P-0775, p. 5.

Ventana Benchmarks. Eastern Health planned to begin the briefings with a statement about what they would not be talking about: individual cases and causative factors.

In preparation for the media technical briefing, Ms. Bonnell and her colleagues drafted a list of anticipated questions, which she forwarded to those involved. She added: "Clearly we will not be able to answer many of these questions, but will need to stick closely to our key messages....we will have drafted answers by Sunday for discussion." By Saturday, December 9, Ms. Bonnell had revised some of the material. As she put it, "following conversations with Nash, Heather, Dan and Oscar, I have revised the original drafts in anticipation of our meeting at 1 p.m. tomorrow." She added:

I guess the most significant change you will note from the original material is the lack of reference to a "rate of error." We can anticipate that this will be a major pressing point with the media, but the approach we will be taking here is that (a) we can't indicate that an error is actually occurred and (b) the whole process wasn't about identifying a rate of error anyways - it was about identifying patients whose treatment would change as a result of the review and the paneling. Hence, the number of individuals impacted has changed from 104 to 117 - taking into account the 13 individuals who had no change in their results but, because of the new definition of positivity, should have been offered tamoxifen ... we won't be spelling that out like that, though.

Re: the dead, we must also be prepared. Our statement will need to be that, in this almost ten year period, individuals have died, either as a result of their breast cancer or for anyone of numerous reasons. We did not retest these individuals because the purpose of the retest was to provide opportunities for individuals who could potentially benefit from a retest. However, if families would like to have their relative's samples retested, we can arrange that for them. We have no way of predicting how many if any of those individuals would not have died had they been offered tamoxifen after their initial treatment for cancer.

Hope all this helps. See you tomorrow.⁹¹

Attached to the email were the agenda for the media technical briefing, a press release, a chronology of events, a Question and Answer

⁹¹ Exhibit P-0184.

document and a note entitled “not about the % of conversion only.” In these documents – as they had indicated they would do – Eastern Health cited ongoing litigation as the reason they could not discuss the review. As to the numbers, only three are mentioned: the total of 2760 cases, with 939 being negative, and the number of patients who had a recommendation for treatment change at the end of the process, that is, 117.

Ms. Deana Stokes-Sullivan represented the *Telegram* at the media technical briefing. Those attending were advised that they could not use cameras or record what was said. They were permitted to take notes. They were provided with a compact disc of Eastern Health’s PowerPoint technical presentation. The oral briefing was done by Dr. Howell, Dr. Denic, and Dr. Laing. It was followed by a tour of the laboratory. The media had earlier been told that they could do interviews after the tour of the laboratory but Ms. Bonnell advised them that the interviews would be the following day and that Eastern Health was going to “embargo” any information until the next day. The media reacted negatively to this and eventually, after much negotiation, there was no embargo.

Ms. Stokes-Sullivan recalled that Eastern Health provided the number of 117 for the treatment changes but refused to give the total number of inaccurate results or to say how many patients had died. Ms. Stokes-Sullivan’s story, which Ms. Barrington characterized on December 12, 2006, as providing the “most accurate coverage,” described the history of the ER/PR problem, the purpose of the tests, the roles taken by Dr. Howell, Dr. Laing, and Dr. Denic during the briefing, the factors involved in determining if tamoxifen should be offered, and the re-testing process at Mount Sinai.

Ms. Stokes-Sullivan’s story contains certain themes Eastern Health promoted:

Howell said it's difficult to assign blame when, in addition to new technology being available for hormone testing, the definition of what constitutes a positive lab result has also changed in recent years.

At one point, he said, a positive diagnosis was made when 30 per cent of cells on a slide took up the stain used to identify hormone receptors. Later that was lowered to 10 per cent and some labs even interpret one per cent as enough for a positive result.

Besides collecting, sending, retesting and reviewing all samples, Eastern Health says it has also conducted an extensive quality review within its immunohistochemistry laboratory.

Howell said this quality review was completed in November, but much of the information is “protected information.” He said it was important that people felt free to be open with their comments.

Denic said Eastern Health is the only health board that he knows of that has undertaken such an extensive retesting of false negatives. Ultimately, he said, the goal has been to improve the standard of practice.⁹²

Ms. Stokes-Sullivan gained the understanding from what was said at the media technical briefing that the problem could be traced to older technology, as represented by the “DAKO system,” which had then been replaced by the new Ventana system. She had the impression that the DAKO system was far more prone to errors. She also thought Eastern Health was saying that ER/PR testing “can produce a lot of false test results.”

In an *Independent* story of December 15, 2006, Ms. Stephanie Porter quotes Dr. Laing as having said: “It really was a systems problem and we’ve done everything we can to fix the problem.”

On December 11, at 8:52 a.m., prior to the media technical briefing, Ms. Bonnell sent to Ms. Mundon the Questions and Answers and the press release. At 10:25 a.m. Ms. Mundon sent the news release on to Mr. Abbott, Ms. Hennessey, Mr. Hynes, and Mr. Osborne. Eleven minutes later she sent to those same people a complete copy of media technical briefing materials Eastern Health had provided to her and advised the Minister that she had printed a copy for him.

⁹² Exhibit P-1087.

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Ms. Mundon provided Mr. Hynes, Ms. Hennessey, Mr. Abbott, and Mr. Osborne with copies of the news coverage arising from the December 11 briefing, including a copy of a transcript of a CBC story in which Mr. Dawe is quoted as noting that this could be a life and death issue. Mr. Dawe also complained that “the lack of disclosure raises questions... about what the problem is and how it can fixed.” Within the Department, Ms. Mundon and Mr. Hynes agreed that Mr. Dawe “has a point.”

The next day, two briefing notes were prepared within the Department of Health and Community Services. One is dated November 27, 2006, but it contains information that could only have been known on December 12. It is not possible to say which of the briefing notes was written first. Both are said to be drafted by Ms. Beverley Griffiths, Board Consultant, Eastern Health, and approved by Ms. Hennessey. In an email of December 12, 2006, Ms. Hennessey advised that she would be late because she was working on revisions to the House of Assembly briefing note based on the press release of the day before. Ms. Hennessey acknowledged that in that process she would have reviewed Eastern Health’s briefing materials and would have been aware that all of the numbers the Minister had been shown in the November 23 meeting were not in the press release. In the briefing note dated December 12, 2006, a reference to the technology having changed over the years and being more sensitive to picking up ER/PR negatives and positives is used. On December 12 a copy of this briefing note was sent by Ms. Mundon to Ms. Matthews “for the Premier’s information.” As it happened, December 12 was the last day of sittings for the House of Assembly for that year. There were no questions asked of Mr. Osborne regarding ER/PR.

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On February 9, 2007, an affidavit sworn by Ms. Predham was filed in the Supreme Court of Newfoundland and Labrador in the class action against Eastern Health. This was something Ms. Predham did not want to do. However, Dr. Williams had retired and his successor, Dr. Howell, was not prepared to swear to provide an affidavit. In the affidavit Ms. Predham pointed out that Eastern Health had no control over the pre-

analytical or fixation phase for specimens from other regional health authorities. The affidavit data included the following:

- 2760 tests done between 1997 and August 2005 were reviewed;
- Of those, 939 were originally reported as negative and were sent to Mount Sinai for re-testing;
- Results were obtained for 763 patients;
- Of the 763 patients, 433 saw no change in ER/PR results and no change in treatment;
- The 433 were broken down as follows:
 - 341 patients were confirmed negative by Mount Sinai
 - 28 patients were confirmed negative by the Panel
 - 12 patients were confirmed positive
 - 52 patients were DCIS and therefore no form of treatment would have been recommended;
- Another 13 patients had no change in results, but a change in treatment was recommended, based on a change from what was considered positive at the time of the original test; and
- Results were different for 317 patients. Of those, 104 required change in treatment, 94 were recommended for tamoxifen or another aromatase inhibitor, four had a change in original diagnosis, and four were retro-converters.

Ms. Predham stated that the remaining 213 patients did not require treatment because:

- 60 had a very low risk of recurrence;
- 148 had previously been treated with tamoxifen or another aromatase inhibitor;
- 13 were not placed on tamoxifen for their original disease but for subsequent metastatic disease; and
- five required assessment before any recommendation could be made.

Ms. Predham then added that 176 of those originally reported as negative are deceased. Of those:

- 101 were re-tested and results had been received;
- two patients' samples had been re-tested on request; and

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- 73 patients would not be re-tested unless the families requested it.

This was, essentially, the information that had been provided to the Minister on November 23, 2006.

Coincidentally, on February 9, 2007, Eastern Health considered a proposal for a crisis communications plan submitted by the Bristol Group Inc. The proposal made the point that “telling the right story is the foundation of success. The messages have to be plausible, supported with substance and compelling.”⁹³ Bristol advocated the CAP formula as the best approach to public communication: demonstrate concern; outline the action which you are going to take to address the problem; and provide perspective – allowing the organization to put the problem in context.

Within Government, the Department of Health and Community Services continued to prepare regular Question and Answer briefing notes on the ER/PR matter for the Minister. The key messages in them continued to support the actions taken by Eastern Health. The position was that since there were legal proceedings, the Government would allow the legal process to determine whether errors had occurred. The idea that the Ventana is more “sensitive to picking up ER/PR negatives and positives” continued to be included. The April 19, 2007, Question and Answer briefing note refers to the fact that an affidavit had been filed in the Supreme Court in connection with the class action suit. There was also an explanation of the change in view, over time, of the percentage of positivity that is deemed to warrant treatment with tamoxifen or some other aromatase inhibitor. It concluded with the statement: “Today, oncologists believe that any positive result is worthy of hormonal therapy.”

On May 15, 2007, Mr. Quinn of the CBC did a story based on the information contained in Ms. Predham’s February 9, 2007, affidavit. Mr. Quinn had been advised of the existence of the affidavit by Ms. Marian Crowley,⁹⁴ of Eastern Health, in a letter of March 16, 2007, in which

⁹³ Exhibit P-1499, p. 6.

⁹⁴ Ms. Crowley was then the Access and Privacy Coordinator at Eastern Health.

Eastern Health denied access to information that had been requested by Mr. Quinn. The affidavit contained many more details than had been provided during the media technical briefing in December 2006.

On May 15, following the airing of Mr. Quinn's story, there were many media requests of Eastern Health for interviews. All were declined. In the House of Assembly the Minister of Health and Community Services was asked questions about the subject. By then, the Minister was Mr. Ross Wiseman. In his statements to the House of Assembly on May 15 he emphasized the changes that had been made, such as dedicated technologists and pathologists, ongoing monitoring, and additional training. He acknowledged that the Department of Health and Community Services had had the numbers quoted by Mr. Quinn in 2006 and maintained that all results were communicated to the patients. In the meantime, within the Department, briefing notes were being revised. Ms. Hennessey directed that "the note" be sent to Ms. Matthews.

Later in the afternoon of May 15, Mr. Tilley emailed the Board of Trustees. He pointed out that the media was focusing on the number 317, which represented the number of cases where the results changed, in contrast to the 117 cases involving a change in treatment, a figure Eastern Health had focused on during the media technical briefing in December. He concluded:

It is believed that the numbers of individual conversions are not relevant and risk turning the process into a "numbers game." For example, some people had minor conversions that did not impact upon whether they would be considered suitable for hormonal therapy. Some individuals converted, but upon review of their treatment plan it was discovered that for other clinical reasons they were already receiving tamoxifen.

We did meet with the Minister of Health this morning and briefed him on the situation. He will likely respond to the media. As you would have expected, on the advice of our legal counsel, we are staying away from any public debate as this issue proceeds through the court process.⁹⁵

⁹⁵ Exhibit P-0106, p. 2.

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Later that evening a member of the Board of Trustees of Eastern Health, who happened to be a lawyer, responded to Mr. Tilley. He had seen the Minister on the news that evening and was unhappy with the Minister's statement that Eastern Health had been advised by its lawyers not to disclose certain information. Mr. William Boyd wrote: "That sounds very bad and makes it appear that we did deliberately mislead. We must respond in my view, to the allegations that we misled the media and the public in our previous disclosures; I think we can do so without prejudicing [sic] the legal case for the defence."⁹⁶

The next morning Mr. Tilley passed Mr. Boyd's advice to Ms. Predham, Dr. Howell, and Ms. Bonnell. Ms. Predham replied, indicating some uncertainty about the right course of action and expressing frustration at comments made by Mr. Dawe and Ms. Lorraine Michael, Leader of the New Democratic Party, the evening before. She concluded by saying:

I guess the key point of clarification is that all the patients who need to know, knows ... it's the general public and the media that doesn't have all the details and that is because it's before the court.⁹⁷

On May 16, the issue of communications was considered at Eastern Health's Executive Management meeting. The minutes record the following:

There has been significant media attention related to the ER/PR receptor testing. On 15 May 2007, George Tilley, Dr. Howell and Heather Predham briefed the Minister on the issue.

Calls from patients will be directed to the Quality Department. Pat Pilgrim will mobilize a team and put a process in place.

The organization will discuss further, outside this forum its communication strategy. Strategic Communications will begin to pull together the key messages in preparation for a potential Press Conference on the issue.⁹⁸

⁹⁶ Exhibit P-0106, p. 2.

⁹⁷ Exhibit P-0106.

⁹⁸ Exhibit P-0286, p. 2.

Within the Department of Health and Community Services, two Question and Answer briefing notes were produced on May 16, 2007. Ms. Hennessey identified the earlier of the two. The first draft contained the numbers provided to Mr. Osborne in the fall of 2006. It noted that the CBC story of May 15 had reported that for the 763 living patients, 42% or more of the test results were wrong (317/763). This was contrasted with information contained in the December 11, 2006, press release of Eastern Health, which stated that 117 of the 939 cases re-tested required treatment changes. These figures, it is pointed out, would suggest a 12% error rate. Key messages contained in the second briefing note include:

Eastern Health was advised by its legal counsel to withhold this information pending court action. Should this information have been provided as part of technical briefing for the media in December 2006 when further information regarding those requiring treatment changes (117) was released? In the spirit of openness and transparency, yes, I believe that it should have been released at that time.

...

The public should have every confidence in Eastern Health. The fact that the authority made a voluntary decision to retest ER/PR results over a period of time goes beyond what has been done anywhere else in the country.

...

Government is satisfied that through two independent reviews already conducted and new quality measures now in place, that this situation will not occur in the future.⁹⁹

In the House of Assembly on May 16, the Minister was asked whether there were patients who had still not received results. The Minister gave the House of Assembly assurances that all patients had been contacted.

At Eastern Health, on May 15, Ms. Nancy Parsons had received an inquiry from a patient who had had ER/PR testing in 1999, inquiring as to what her re-test results were. Ms. Parsons dealt promptly with the request and found the information for the patient. On May 16, the patient, in thanking Ms. Parsons for dealing with her request, suggested

⁹⁹ Exhibit P-0126.

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that patients would appreciate a letter regarding the issue, containing a phone number to contact.

On May 16, 2007, Ms. Bonnell provided a memo to Mr. Tilley, Dr. Howell, and Mr. Stephen Dodge in which she argued for a public response in the face of “our credibility as an organization and our ability to provide quality care” being maligned. She concluded:

However, in December we told the press that we could not (a) release all the numbers or (b) assign a rate of error for this test. The total number of individuals impacted by this retesting is a key part of the legal case and needs to be dealt with in court – not in the press. Secondly, we cannot assign a “rate of error” for this test. Error will need to be determined by the courts. We had said repeatedly in the media that we do not know with certainty what caused there to be new or differing results.

From the beginning, our focus was on answering the question – whose treatment plan may require a change? That question has been asked and answered and every single individual impacted has been contacted through their physician.¹⁰⁰

In an email to Ms. Mundon on May 16, Ms. Bonnell addressed what had been said at the December 2006 media briefing:

Old email around the time of the media briefing. Note that almost all the reporters reference the fact that we will not reveal how many women had a false report, only that 117 had treatment changes. In the briefing, this obviously came up. We were asked by Mark Quinn and others if there were more than 117 women whose test results changed and we did tell them yes, but that the # was not relevant or available to provide due to the pending litigation. Here's the prepared q and a on this issue, which as I recall we stuck to like glue:

Q9. What is the rate of error? How many people converted?

A9. Up to this point, our focus has been on making treatment changes, where appropriate, and 117 individuals have experienced treatment changes.

Some of these changes are because of a conversion in their ER/PR test result from negative to positive; some because the definition of "negative" has

¹⁰⁰ Exhibit P-0012.

changed; some because of where patients are today with their disease - there are multiple factors involved.

Now that legal proceedings have been initiated, we will have to allow the legal process to determine if in fact error has occurred.

The numbers of individual conversions are not relevant and turn the process into a "numbers game." For example, some people have minor conversions that did not impact upon whether they would be considered suitable for hormonal therapy. Some individuals converted, but upon review of their treatment plan it was discovered that for other clinical reasons they were already receiving tamoxifen.

What is relevant is the number of people whose care may change as a result of the process, and that was 117.¹⁰¹

On May 17, 2007, Mr. Abbott gave a presentation to Cabinet on the issue. Mr. Abbott's presentation started with a summary of the history of the ER/PR problem. He then proceeded to address what the Department knew and when. This part of the presentation included reference to a number of meetings with various Ministers and to briefing notes prepared within Eastern Health or the Department during the previous two years. He summarized the public communications on the issue and the quality assurance efforts that had been implemented by Eastern Health in response to the problem. During the presentation, Mr. Osborne stated that he had never seen the August 18, 2006, briefing note for Cabinet Secretariat. This statement was greeted with some scepticism, particularly by the Premier. However, later that day Mr. Abbott and Ms. Hennessey confirmed for Premier Williams that the note had not been sent to Mr. Osborne. Mr. Osborne was in the habit of carefully reading briefing notes prepared for him. He no doubt would have read the August 18, 2006, briefing note had it been sent to him. Having read the briefing note, he would have realized that the statement that "22 women were impacted by the change in status of the ER/PR receptor tests" was inconsistent with the information that he had been given prior to that.

¹⁰¹ Exhibit P-0825.

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At the conclusion of the meeting, Cabinet directed the Minister of Health and Community Services to instruct Eastern Health to provide a technical briefing to media and other interested parties on this matter.

On May 17, a Question and Answer briefing note was prepared for the Minister in light of the comments in the preceding two days. The key messages included:

There was full disclosure with patients and their families once test results became available.

In the House of Assembly on that day there were more questions about the subject. In the process of answering questions, the Minister stated that he had asked Eastern Health to hold a full briefing the next day. Eastern Health was also advised, on May 17, that there was a commitment to brief the Opposition, which Ms. Mundon suggested be done separately from the press briefing.

The media briefing was held on May 18. It began with a prepared statement by Mr. Tilley. Other than the written statement for the *Current* and his presentation to the CPSI conference, this was the first time that Mr. Tilley had spoken publicly on the subject. Among the points made by Mr. Tilley was that Eastern Health had “contacted each and every patient who was affected by the ER/PR test review, making sure they received all the information and the support they required.” He added:

Before we talked about our results with the public we felt that had an obligation to contact each and every patient who was involved in the retesting to tell them either:

- that their tissue had been retested and there was no change in the original results;
- that their tissue had been tested and that we were recommending a change in their treatment; or
- that although there was a change from their original test result, no change in treatment was recommended.

This process was never a research project.

Nor was it [a] quality review exercise.¹⁰²

It was about this organization redoing a test to provide every treatment opportunity possible for our patients.¹⁰³

On this occasion Eastern Health finally publicly discussed the numbers that had been given to Mr. Osborne in the fall of 2006. In the package provided to the media on May 18, the numbers were set out essentially in the same manner that they had been set out in Ms. Predham's February 9, 2007, affidavit. However, on this occasion there was additional information regarding the deceased. In November 2006, the information regarding the deceased had been that there were a total of 176, 105 of whom had been re-tested during the process, including two on request: the balance would be re-tested at the request of the families.¹⁰⁴ On this occasion, for the first time, Eastern Health revealed a breakdown of the results of the 105 deceased patients' re-tests: 68 were unchanged, that is, confirmed negative; one was a false positive, and 36 changed from clinically negative to clinically positive on re-test. There was no updating of the number of deceased.

The May 18 press package also included an "ER/PR Chronology."¹⁰⁵ The chronology began with the installation of the "Ventana system" in 2004, replacing the "Dako System, a complicated, manual and multi-phase procedure with more than 40 steps." The document also referred to the "more sensitive Ventana system."

The "ER/PR Chronology" also included a description of what had been occurring in the latter half of 2006:

¹⁰² This may have been Mr. Tilley's view at the time but that was not always the way it was portrayed by Eastern Health. For example, in October 2005 Mr. Boone expressed concerns about referring to a quality review in correspondence and with characterizing the re-testing of samples as part of the quality review. In passing this advice along, Ms. Predham noted "I figured we might as well say quality review since Dr. Williams has been saying it all along ..."

¹⁰³ Exhibit P-0443, p. 4.

¹⁰⁴ For some reason, the total of 939 used by Eastern Health had always been calculated as if the 176 deceased had all been re-tested, which of course was not the case.

¹⁰⁵ Exhibit P-0843.

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September 2006: A statistical review was initiated to examine the numbers and arrive at conclusions. This information will form the basis of the quality review. Analysis is continuing.¹⁰⁶

Late November 2006: The organization completes its quality review.

December 2006: Public release of results and media briefing.

February 1, 2007: Testing begins again in our laboratory.¹⁰⁷

The briefing for Members of the House of Assembly was set for the following Tuesday. Eastern Health did not want it to be advertised as a public briefing.

Within Government, consideration was being given to the options available to Government, should it wish to have a review conducted of the ER/PR matter.

On May 18, as a result of the new publicity about ER/PR, Eastern Health was dealing with many calls from patients and relatives. In a memo of that date, Ms. Predham notes: "I'm assuming that Nash [Denic] is making arrangements to retest the rest of the deceased?" At both Eastern Health and Government the press response was being closely monitored.

Among the media stories was one from CBC Newsworld that included quotes from Mr. Tilley's remarks at the press conference on May 18. Among those are the following regarding the review conducted by Dr. Banerjee and Ms. Wegrynowski:

We saw a change in results for three hundred and seventeen patients. And as you point out, there is an element of uncertainty in this particular test and it's quite well-known both nationally and internationally. When we first became aware of this and decided to suspend treatment our physicians and technologists spent a great deal of time looking inside the organization, looking at the procedure for that test. We also sought the input of technologists, a technologist and a physician more independent of the organization, to come and give us an objective assessment as to what we do and how we do it... I

¹⁰⁶ No such review occurred in 2006-2007.

¹⁰⁷ Exhibit P-1416, p. 3.

recall that the comments of the physician were that he considered us to be in the middle of the pack in terms of laboratory services with regards to ERPR. And to be quite frank with you, we're not satisfied with being in the middle of the pack, we are interested in becoming amongst the top laboratories for this procedure in the country. Having said that, the individual, individuals who are not able to point to a technique, a person, a discipline that had done anything that would suggest that errors would occur. And unfortunately, because of that, we have to look at this problem in terms of what can we do to make improvements in the system to restore our comfort and the public's confidence in that procedure. So what we have spent a great deal of time doing is looking at other centers in the country for whom we, us and others feel that they have centers of excellence, to look at what they've done and implemented it here.¹⁰⁸

By coincidence, also on May 18, 2007, Mr. Wiseman, was writing to the president of the NLMA on the subject of salaries for pathologists, which had been a subject of discussion for some time prior to this. In the letter the Minister advised the NLMA that Treasury Board had recently approved the proposal of the Department of Health and Community Services to extend the oncology stipend under the salaried physicians policy to the province's salaried pathologists, effective February 26, 2007. This was the culmination of much work directed to improving the salary for pathologists. It had been argued that the salary level in Newfoundland and Labrador was contributing to the problems in recruiting and retaining pathologists.

By May 22, the day of the briefing of the members of the House of Assembly, within Government the communications people were preparing for an announcement of the appointment of a Commission of Inquiry. Efforts were being made to ensure the information contained in the release was precise.

A backgrounder attached to the May 22 media release included a statement that Eastern Health had committed to re-test results for the 176 deceased patients "and to ensure that all patients' families were contacted for follow up." In the House of Assembly that day the Minister answered questions. In responding to questions regarding legal advice, the Minister said:

¹⁰⁸ Exhibit P-0110, p. 3.

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The issue here, in terms of legal opinion, Eastern Health have their own solicitors. Eastern Health sought their own legal advice, from their own law firm who provides advice to them. They, in turn, got their legal advice directly from their own solicitors. Any reference I have ever made to legal counsel has always been referenced to what legal advice Eastern Health received. Eastern Health received their own independent legal advice from their own law firm and any legal advice on this issue has been provided by their firm.

Later he added:

I had said clearly that the Department of Health and Community Services, as a department, has not asked the Department of Justice, as a department, for a legal opinion on this issue. Period. That is crystal clear. It identifies that the department has not sought legal advice.¹⁰⁹

On May 24, the issue remained a topic in the House of Assembly. Within Eastern Health the organization was concerned with “inaccurate coverage.” An undated briefing note on the subject of crisis communications, believed to have been completed in late May 2007, points out that “the health authority cannot begin to rebuild its image or restore public faith in the system until the immediate crisis has been stabilized.” A plan was outlined, including the use of full page advertisements which “will focus on correcting three main inaccuracies currently reported in the media. These include: Eastern Health did fully disclose the ER/PR issue to the affected patients in a timely fashion; neither the ER/PR issue nor radiologist’s suspension affects women who have undertaken mammography screening; and Eastern Health upholds the highest standards of patient care and is confident in the quality of its laboratory services.”

One of the stories that caused concern had appeared in the *Globe and Mail*, which reported that the government had for two years failed to disclose fully information regarding faulty breast cancer testing that took place from 1997 to 2005. Both the Minister and Mr. Tilley sent letters to that newspaper in response.

¹⁰⁹ Exhibit P-0105, pp. 38-41.

Mr. Wiseman wrote that there had been full disclosure to patients and their families: “Each patient affected by the test review were told directly, or through their family physician, one of three things: that their tissue had been retested and there was no change in the original results; that their tissue had been retested and Eastern Health was recommending a change in their treatment; or that there was a change from their original test result but no change in treatment was recommended.”¹¹⁰ His letter also referred to a new laboratory having been created with new equipment, and the term “centre of excellence” was utilized to describe the laboratory.

The advertisement to be placed in newspapers by Eastern Health was reviewed within the Department of Health and Community Services and by Mr. Thompson and Ms. Matthews. Ms. Matthews recommended that emphasis be placed on the point that all patients had been fully informed. The advertisement, which appeared in newspapers throughout the province over the following week, read in part:

We have heard all the recent media coverage concerning our testing. We want to make sure that you have the right information.

We have heard from patients who are concerned about their mammograms or worried about breast cancer diagnosis. **These issues are NOT connected in any way with mammography or breast cancer screening.** Estrogen and progesterone (ER/PR) tests help determine treatment options for breast cancer patients.

WE HAVE ALWAYS BEEN UP FRONT AND OPEN WITH OUR PATIENTS

An impression has been left with the public that patients affected by the ER/PR review were not contacted or given their own health information. This is not true.

Disclosure is an important and valued part of the health care system in general and to us in particular.

¹¹⁰ Exhibit P-0458.

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Our first priority is and always has been quality patient care. That's why in 2005, when these issues came to our attention we acted immediately to put safeguards in place.

- We stopped testing in our lab until a quality review could be completed;
- We called all patients whose samples were being re-tested;
- We talked about the issue in the media;
- We posted information on our website;
- We set-up an inquiries line so every patient's concern could be heard;
- We informed all patients and their doctors of their individual test results; and
- We invited international experts into our lab to review our processes.¹¹¹

Also on May 24, Dr. Howell forwarded to Mr. Abbott a copy of Dr. Ejeckam's memo of June 19, 2003.

After the advertisement appeared, questions were raised in the House of Assembly about whether it was misleading in stating that all patients and their doctors had been informed of the results. In considering the proper response, Mr. Thompson raised the question of whether it was possible that some of the physicians who had been contacted had not contacted their patients about the results. Ms. Bonnell, however, confirmed to Ms. Mundon that there had been follow up by Eastern Health with physicians to ensure that the patients had been contacted.

On June 7, 2007, Mr. Thompson emailed Mr. Tilley, asking him how they could reconcile the claims of Eastern Health that all patients had been contacted and the claims in the media that patients had not been contacted. Ms. Predham was among those to whom Mr. Tilley turned for information. She said:

Between our list and the calls that we received we felt we had a comprehensive list of all those scheduled to be retested. However, during the past two years we have gotten an occasional call from someone who did not make the original list. There have been a variety of reasons.

¹¹¹ Exhibit P-0343, p. 4.

I must note that we still get calls from people who say they weren't called, but who were always ER positive and not part of the retesting.

When the results came back, the patients who were confirmed negative were notified by the particular region, while the patients whose results were changed were notified by letter through their physician.

On June 7, 2007, Mr. Thompson replied:

The return email has unnerved us. Let me explain.

In December 2006 Eastern health told the media that in October 2005 "Patient Relations representatives ... telephoned all individuals whose specimens were being sent away for retesting."

Mr. Thompson noted that on May 18, 2007, Eastern Health repeated this message to the media.

On the basis of these confirmations from Eastern Health, we assumed that the "763 patients whose samples were retested" were all called in October 2005.

There has been some uncertainty on this point in public because of patient statements in the media...

Mr. Thompson then cited two examples where patients indicated that they were not contacted, and added in respect of Ms. Predham's reply:

...Ms. Predham says: "In October 2005, all patients that were identified at that time as part of the retesting, were contacted by our department (QRM)." She also says: "Between our list and the calls that we received we felt we had a comprehensive list of all those scheduled to be retested." And she says, "However, during the past two years we have gotten an occasional call from someone who did not make the original list. There have been a variety of reasons."

These three statements are qualified statements.

Therefore, we need to receive from you this afternoon the exact number of patients that were contacted in October 2005, out of the total of 763. If there were any patients not contacted in October 2005, when were they contacted since that time.

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As you can appreciate, this is very important to determine with great urgency. Please call me when you have read this email. Thanks.¹¹²

About an hour later Mr. Thompson emailed Mr. Wiseman, Ms. Hennessey, Ms. Mundon, Ms. Matthews, and Mr. Crawley reporting on a conversation he had had with Ms. Predham and Mr. Tilley. Mr. Thompson provided the detail given to him by Eastern Health. He then concluded:

... we are informed by Eastern Health that all people who had been identified for re-tests by October 2005 were called in October 2005, except for some people whose results were already back from Mount Sinai. Some more people (though we are told it was a small number) were identified after October 2005 and may not have been called. It is unfortunate that Eastern Health did not raise these qualifications in their media briefings because it leaves the impression that 100% of the 763 re-tested patients were called, when in actual fact there is some degree of variation from this absolute level. Furthermore, the total of 763 was not known in October 2005; it was first used in December 2006.¹¹³

While the creation of a Commission of Inquiry might be viewed by some as a questioning by Government of Eastern Health's handling of the ER/PR problems, in my view this email exchange in early June 2007 marked the first genuine questioning by government officials of what had been done, or, more accurately, said. This questioning of the veracity of Eastern Health's statements regarding contact with patients caused government to embark on inquiries that involved NLCHI, as well as further investigative efforts by the four regional health authorities that extended well into 2008.

¹¹² Exhibit P-0471.

¹¹³ Exhibit P-0233.

Chapter Eleven

Communications Part II: What They Were Told

Communications Part II: What They Were Told

Communication with Patients

That there was to be a re-test

As the previous chapter demonstrated, when it was determined that the ER/PR problem potentially involved hundreds of patients, discussion took place within the Group about the need to communicate with the patients. There was, however, a great deal of vacillation about the subject. Dr. Williams' first instinct was to make a public announcement that the re-testing was to take place, to be followed later by a letter to each patient being re-tested. He felt this was the only practical way to deal with a situation involving such a large number of patients. It was Mr. Tilley who, at least in the materials provided to the Commission, first articulated the need for more information before such an announcement was to be made, but he had allies within the Group. As discussed, HIROC cautioned against a letter advising patients that there would be a re-test and suggested Eastern Health wait until the re-test results were available before contacting patients. Later still, the oncologists' view that there should be no announcement or notification that testing would take place became the position of Eastern Health. That position, if not expressly endorsed, was accepted by Government. When the matter became public on October 2, 2005, as a result of the *Independent* story, the debate about how to communicate with the patients arose again. Finally, on October 18, 2005, the debate ended when it was decided that there would be telephone calls to those patients being re-tested. The notion of sending letters directly to patients did not arise again until 2008.

All of those calls were made from Eastern Health by staff of the Quality Department. Four people made the calls, including Ms. Predham. While I have no difficulty with the staff of the Quality Department making patient contacts, it is problematic that Ms. Predham, who was the liaison with HIROC for Eastern Health, was involved.

The four callers had little preparation for the task. They attempted to answer any questions a patient might have. It is fair to say that they learned more and more about the ER/PR matter as they went along. Ms. Nancy Parsons, one of those doing the calling, said that if patients asked, she advised them that they would have the re-test results before Christmas. By the time that the calls began, some of the test results had been returned from Mount Sinai and, for a few patients, the first call actually advised that there was no change in their hormone receptor status following the re-test. One of the patients who received a phone call to notify him of the re-testing was Mr. Norman White.

Norman White: It affected men too

Mr. White, a retired Western Memorial Hospital biomedical technician, resides in Summerside, Newfoundland and Labrador. Mr. White was diagnosed with breast cancer in July 1999 and within weeks of diagnosis he underwent a radical mastectomy at Western Memorial. At the time of his diagnosis, Mr. White was advised that he was hormone receptor negative, in that he was estrogen receptor positive in 1% - 5% of cells and PR negative. He did not receive any further treatment but was followed up on a regular basis at the Cancer Clinic at Western Memorial Hospital for a time. On his chart there is a draft "initial visit summary" dated August 13, 1999, for Dr. Younous' signature. Dr. Younous, however, never saw Mr. White. This draft report noted that the ER/PR result was not yet available but if it was positive, the recommendation may be to continue with tamoxifen, or that he could be followed without any further intervention.

Mr. White's case differs from that of most patients in that his consent was sought to carry out a re-test of his tissue sample. In the summer or early fall of 2005, he received a phone call from a woman at Eastern Health seeking his permission to have his sample re-tested. This was how he learned of the ER/PR issue. The NLCHI database indicates that Mr. White was contacted by Ms. Bonnie Walker of Western Memorial on December 6, 2005.

Mr. White's case was reviewed by the Panel on March 4, 2006. A panel letter dated March 6, 2006, was addressed to Dr. Pradip Ganguly for follow-up. As Mr. White had a low risk of recurrence, the Panel did not recommend any hormonal therapy, notwithstanding the change in his ER result. Mr. White moved to Alberta on March 14, 2006. As a result, Dr. Ganguly's attempts to reach him to follow up on the panel letter were unsuccessful. It was not until October 2006 that Mr. White was informed, by his general practitioner, that he had been re-tested and his ER result had changed to 60% positive. Mr. White was not offered a meeting or discussion with an oncologist to discuss this result. He feels he has many unanswered questions, such as why he was not a candidate for hormonal therapy even though his results had changed.

The results of the re-test

When the re-test results began to be returned to Newfoundland and Labrador, how and by whom one was told of the results was primarily determined by the results themselves and by the hospital the original specimen came from. The largest single group of patients included those whose test results remained negative. Eastern Health decided that staff of the Quality Department, would telephone each "confirmed negative" patient.¹ If there was a clinically significant change in results, the case was reviewed by a group of physicians (the Panel). In fact, the process led to the development, within Eastern Health, of the verb "to panel," meaning to have one's case reviewed by the Panel.

Ms. Parsons was, once again, one of those who called patients, this time to say that the test results were unchanged. A script was prepared to assist those who phoned patients. Having identified themselves, the callers first determined whether the patients were already familiar with the re-testing process. If the patients were not, they would explain, much as was done in the earlier calls telling patients about the re-test. They would then move on to discuss the re-test results. The script included the following lines: "Your previous test results indicated that you are

¹ The exceptions were confirmed negative patients whose specimens originated with a hospital operated by Western Health or Central Health. Each of those regional health authorities was responsible for calling its own confirmed negative patients.

negative for ER and PR.² We are pleased to tell you that we have your results back and there is no change from what they were originally. Everything remained the same for you, so no new treatment is necessary at this time. You just need to continue with your checkups the same as you have been doing all along.”³ Patients were, once again, given Ms. Parsons’ telephone number to call if there were additional questions. Ms. Parsons understood the news she was delivering was good news. She was reassuring patients that the results were correct the first time. It was an interesting incongruity that Eastern Health, which had stated that it undertook the re-testing to ensure that no treatment options for patients were missed, chose to tell those patients that they were pleased to advise that an additional option was not available to them.

Ms. Parsons, in her capacity as patient relations officer, dealt with general telephone inquiries. She also dealt with the telephone inquiries from patients who had questions about ER/PR testing. In fact, when the calls were made to inform patients of the re-test, it was Ms. Parsons’ telephone number that was provided to patients so that if they had questions they might have a contact at Eastern Health. She explained that when she received inquiries or complaints, she would take information she could use to identify the patient, such as a date of birth or an MCP number, which would enable her to access the information to determine first if she could herself answer the patient’s questions. She was able to access Meditech for the St. John’s hospitals to view pathology reports, but she had no access to the OPIS system at the Cancer Centre or the data from other regional health authorities. In those cases she would have to call to obtain the information. Later in the fall of 2005, she received many calls from patients seeking their results. Because of the delay in obtaining results, often the answer was that the results were not yet back.

Ms. Parsons, who is a registered nurse, felt comfortable telling patients that their results were unchanged but believed that it was beyond the scope of practice of a nurse to tell patients that there had been

² In fact, a criterion for testing was a negative result for ER. A number of the patients were PR positive.

³ Exhibit P-2899.

a change in their test results. She believed that information should come from a physician. Ms. Parsons therefore developed a way of dealing with such patients if they called her number. If she saw that there was a change in results, she would say that she had nothing to tell them. However, Ms. Parsons would not leave it at that. If she determined, during the conversation or perhaps because there were many conversations, that a particular patient was worried about the matter, she made efforts to see where in the Panel process the case was located and, on some occasions, asked that the Panel deal with the case on a urgent basis.

Ms. Parsons, and anyone else in Eastern Health who thought about it, knew that there would be questions about what caused the problem. Ms. Parsons had no personal knowledge of what had occurred and she was given no information to provide to the patients. She did not know anything about ER/PR before the problem arose. When she was asked “how did this happen?” she explained that Eastern Health did not really know. She might say that the test was a complicated one, with many steps, and Eastern Health was checking to see whether something had gone wrong in the laboratory. Ms. Parsons based her response on conversations she had had with Ms. Predham. She said that whenever she asked Ms. Predham for information regarding the cause of the problem, Ms. Predham’s response was: “we still don’t know.”

Of those who made the calls to patients, only Ms. Predham and Ms. Parsons testified at the Inquiry. Of those two, Ms. Parsons made many more calls and talked to many more patients. One can see why she was chosen to be a patient relations officer. She has a calm and empathic manner which no doubt was reassuring to patients, the very point emphasized by those who argued for personal contact. I was struck, however, by the contrast between the preparation of spokespersons for Eastern Health who were to give media interviews or appear at briefings or press conferences, and that given to Ms. Parsons and others in the Quality Department who were to make individual contact with the patients. The only real assistance given those in the Quality Department was the suggested script to be used to tell patients that their test results were unchanged. Those who worked in the Quality Department,

including Ms. Predham, knew about the weakness of this method of communication. The idea of following up the conversation with a letter was not considered,⁴ though it was clear that a number of patients had further questions or, in spite of the fact that they seemed to understand at the end of the initial conversation, later demonstrated that they had not understood what they were initially told. Ms. Patricia Goobie was one of these patients.

The Story of Two Sisters: Patricia Goobie and Geraldine Avery

Ms. Patricia Goobie resides in Queen's Cove, Newfoundland and Labrador. She was diagnosed with breast cancer in June 2001 in Clarenville. Her sister, Ms. Geraldine Avery, was also a breast cancer patient. She was diagnosed in 1999 and succumbed to cancer in August 2006 after recurrences in 2002 and 2005. In testifying before the Commission, Ms. Goobie wanted to speak on behalf of herself and her sister.

Both Ms. Goobie and Ms. Avery were found to be ER negative at the time of their original diagnosis. Unbeknownst to Ms. Goobie at the time, her original ER/PR test had been performed at Mount Sinai. Ms. Goobie's result was ER less than 5% positive, which was treated as clinically negative. Ms. Goobie underwent surgery and a course of what she understood to be "precautionary" chemotherapy. She was followed up by her general practitioner. Ms. Avery's sample was tested in St. John's. Her medical journey was much more complicated.

Ms. Avery was diagnosed in 1999 with inflammatory carcinoma of the right breast. Testing at that time found her to be ER/PR negative and strongly HER 2 positive. She underwent chemotherapy, surgery, and radiation. In 2002 she was diagnosed with DCIS of the left breast. In January 2005, she was diagnosed with invasive cancer to the left chest wall. Testing on this sample found Ms. Avery to be strongly ER positive.

⁴ A patient suggested the idea to Ms. Parsons who, in turn, passed the suggestion along, but no consideration seemed to have been given to pursuing the notion of a follow-up letter to patients.

She was then placed on tamoxifen. She did not receive chemotherapy for this cancer. In October 2005, she was diagnosed with gastric carcinoma.

Ms. Goobie and her sister learned of the ER/PR re-testing issue through the media. After hearing that some of the results were back, Ms. Goobie called Eastern Health and was promptly advised by Ms. Nancy Parsons that her results were negative.⁵ She understood this meant she had been re-tested and this was the result of the re-test. She interpreted this as good news. She recalls being told, "Yours is ok. Everything came back negative."⁶ In fact, Ms. Goobie's sample had never been re-tested because her original hormone receptor testing had been done at Mount Sinai.

After receiving her own news, Ms. Goobie phoned her sister and told her the re-test results were available. Ms. Avery called to get her results but was told they were not back. Ms. Avery made several calls to Eastern Health and told Ms. Goobie that she felt she was getting "a runaround." After several weeks of attempting to get answers, Ms. Avery was advised in a telephone conversation with Dr. McCarthy that her results had converted. Ms. Goobie felt her sister should have been given this news in a face-to-face meeting. A Progress Note to Ms. Avery's chart dated December 14, 2005, by Dr. McCarthy states that Ms. Avery was not seen on that day but she had had a discussion with her. The note states, "ER/PR from the first cancer in 1999 which was originally felt to be negative converted to ER/PR positive on retesting... I have discussed with Geraldine the fact that her ER/PR is converted to ER/PR positive. She understands the implications of this. I will discuss this with her further at her visit after her third cycle of chemo."⁷ There is no evidence that Ms. Avery's case was considered by the Panel.

Notes of Ms. Nancy Parsons of a telephone conversation with Ms. Goobie on February 26, 2008 indicate that Ms. Parsons informed Ms. Goobie of her original Mount Sinai results. Ms. Goobie testified that she had called back a second time to Eastern Health and understood the

⁵ Exhibit C-0053, record of telephone discussion October 24, 2005.

⁶ Transcript of testimony, Patricia Goobie, March 20, 2008, p. 21.

⁷ Exhibit C-0055, p. 20.

same message: that she had been re-tested and her results remained negative.⁸ Whatever was communicated to Ms. Goobie, she clearly did not understand that these were her original ER/PR results and not results from a re-test at Mount Sinai. It is easy to understand how Ms. Goobie would be confused when she heard reference to Mount Sinai having done the testing. This situation demonstrates the advisability of sending a letter to the patient to confirm the information that has been verbally relayed.

The Panel

The idea

Dr. Williams credits Dr. Laing and Dr. Alan Kwan with the idea of establishing a panel of physicians who would review the medical history of those persons whose test results changed from clinically negative to clinically positive. Dr. Laing gives the credit to Dr. Kwan, who said that it was first discussed with Dr. Williams about two or three weeks before the first meeting of the Panel on October 13, 2005. Dr. Laing recalled that the idea came out of a recognition that while some of the patients re-tested would be followed by oncologists or surgeons who deal regularly with cancer patients, “some would be followed by family physicians.” Her understanding was that the Panel was a way of providing for those family physicians the kind of opportunity an oncologist would have to consult others in the forum of the tumour board rounds. The regular Wednesday morning tumour board rounds were already busy, so it was decided to have these special rounds where they could ensure that there was someone present to review pathology and patients could be reviewed “in a more timely manner.”⁹ Dr. Laing appears to have been correct in her assessment that the Panel would be more efficient than regular tumour board rounds. As it turned out, the average time per patient file during the Panel process was about eight minutes.

The idea was that after reviewing the medical history of the patient, the Panel would make recommendations regarding the most

⁸ Transcript of testimony, Patricia Goobie, March 20, 2008, p. 68.

⁹ Transcript of testimony, Dr. Kara Laing, September 17, 2008, p. 41.

appropriate treatment for the patient. A letter would be written to the physician identified as the treating physician, conveying the recommendation of the Panel. The “Panel” was also referred to by a number of other names. Often, within Eastern Health, it was referred to as the physician review panel.

Dr. Williams made two points about the idea for the Panel: it was a method of short-circuiting anticipated calls from treating physicians who would want assistance about what to do in the circumstances and it was not intended to interfere with the decision-making process between a physician and a patient. The recommendation of the Panel would merely provide another “level of input” to the physician and patient making a decision.

The Panel Members

Initially, the Panel comprised Dr. Laing, Dr. Joy McCarthy, Dr. Zulfigar, Dr. Pradip Ganguly, Dr. Kwan, Dr. Al Felix, Dr. Cook, Dr. Carter, and Ms. Predham. The first three are medical oncologists. Dr. Ganguly is a radiation oncologist. Dr. Kwan and Dr. Felix are surgeons. Dr. Cook and Dr. Carter are pathologists. Dr. Cook was described by Dr. Williams as an ex officio member of the Panel. He and Dr. Carter, when she attended, were expected to have the relevant pathology reports and to provide any additional information regarding the reports requested by the other members of the Panel. Ms. Predham’s role was described by Dr. Laing as “to help identify the patients who were the confirmed negatives” and to be a link to the other group within the Quality Department who were also contacting patients.

I again note my concern regarding Ms. Predham, as liaison with HIROC, being involved in a process in which decisions were made regarding the impact of the ER/PR problems on patients. Later in the process, Ms. Predham ceased to be a member of the Panel and Ms. Sharon Smith of the Cancer Centre replaced her. Generally, Dr. Laing chaired the Panel meetings. The recording secretary was Ms. Debbie Parsons. Dr. Ganguly seems to have attended only the first meeting. In Dr. Laing’s view, neither Dr. Cook (and presumably Dr. Carter), nor Ms.

Predham (and presumably Ms. Smith) had any part in forming the Panel's recommendations.

How the Panel worked

At the first meeting of the Panel on October 13, 2005, the Group discussed how they would go about their task. Certain principles were agreed upon:

1. the discussions would be recorded in the form of minutes, which could serve as a record of its activities;
2. the referring physician should be notified of the recommendation and the primary cancer-treating physician would be responsible for follow up on the recommendations;
3. notification would be in writing [a panel letter] and a mechanism would be put in place to confirm that the follow-up physician had received notification;
4. the letter would give the primary care physician the option of referring the patient to an oncologist at the Cancer Centre; and
5. treatment would be based on the TAM-02 trial.¹⁰

As the Panel did its work, certain adaptations and modifications were made. For example, as of February 2, 2006, no further minutes were kept of the meetings of the Panel. Rather, Ms. Debbie Parsons recorded, on a spreadsheet, sufficient information to enable her to draft the panel letters, which were then signed by the person who chaired the meeting. Generally, the letters requested that the physician communicate the information to the patient as soon as possible.

The Panel was to review cases where there had been a change in results. Initially, there was some pre-meeting vetting of cases by Dr.

¹⁰ Exhibit P-2457. Not unexpectedly, there have not been many studies on the effectiveness of commencing to take tamoxifen years after removal of malignant breast tumours. The TAM-02 trial was the study which had convinced the oncologists at Eastern Health that there could be benefit to patients who had not initially been prescribed tamoxifen if they were to be given the drug up to 10 years after initial diagnosis. If tamoxifen were contraindicated, other drugs could be beneficial.

Laing or Dr. McCarthy and Ms. Predham. Ms. Predham looked to the oncologists to tell her which patients needed to be considered by the Panel (that is, whether they were considered to have changed results according to the criteria). During those meetings, Dr. Laing or Dr. McCarthy might see a report regarding her own patient and advise Ms. Predham that she would take care of notifying that patient. In January 2006, when large numbers of re-test results were being received from Mount Sinai, the Panel decided that from then on, all changed results would come before the Panel. From that point on, Ms. Predham merely brought all the cases she knew fell or might fall within the Panel's work with her when she came to the meeting. Consequently, in the statistics regarding the Panel's work, there is a relatively small number which is said to be those who were confirmed negative by the Panel. Those who were confirmed negative by the Panel were phoned by Eastern Health's Quality Department or by someone designated to do so in Central Health or Western Health.

Recording results on the basis of panel decisions

The Panel reviewed a patient's chart to determine if there was to be a recommendation for a change in treatment. It is clear that the medical oncologists were the dominant forces on the Panel. This was to be expected, as it is medical oncologists who generally determine whether anti-hormonal therapy should be offered to a patient.¹¹ There are minutes for fourteen of the Panel meetings. At four of those fourteen meetings, there was only one oncologist in attendance.

Information management became problematic in the Panel process as well. The Panel needed updated medical information if the recommendations were to be of any value. Complete information was not always available. At times, the Panel had to seek additional information or qualify the recommendation because of lack of information. As for the data produced by the Panel's work, the focus on recommendations made any other type of analysis difficult. Some examples follow:

¹¹ I would note the usefulness of following all patients whose treatment changed as a result of the paneling process. As with the TAM-02 trial, future insight could be gained for example from the effectiveness of treatment initiated so long after a patient's initial diagnosis.

Hormone Receptor Testing

- a) A woman who had been ER negative originally and became ER positive on re-test might have already been taking tamoxifen on the basis of having been PR positive when the original test was done. Those people, dubbed by Dr. Laing as the “saved by the PRs,” were recorded by the Panel as having no change in treatment, though the case may have involved an egregious error in the original ER result.
- b) There were people who were ER and PR negative originally but who, between the original test and the re-test, had been put on tamoxifen or some similar drug. This scenario generally occurred because the patient, between the original test and the re-test, had had a recurrence of cancer and been tested for ER/PR at that time. Such patients would be described in the panel letters as requiring no change in treatment, though all involved in the process at Eastern Health recognized that they were among the ones potentially the most affected by the original incorrect result.
- c) There were, as alluded to above, cases in which the patient had been seen by a treating oncologist who was aware of the re-test results and had changed the treatment prior to the review by the Panel. Those cases, when paneled, were recorded as having no treatment change recommended, though the treatment change may have been made only weeks, or even days, before the Panel discussion. There were also, particularly in October 2005, some patients whom Dr. McCarthy or Dr. Laing decided to tell themselves. Though they changed from clinically negative to clinically positive, they did not go through the Panel process and were not “officially paneled.”
- d) There were cases where the record revealed that the patients had been offered tamoxifen on the basis of PR positive results on the original test but had refused to take it. In a few of those cases the Panel did not recommend a change in treatment, on the basis that the patient had already refused tamoxifen. In my view, if that prior refusal was the only reason for the recommendation, those

patients should have once again been offered tamoxifen. As has been explained, whether to recommend that a patient be offered tamoxifen is a matter of the doctor and patient balancing many factors. If a patient decided not to take tamoxifen when the ER was less than 10% positive, a clinically positive result might, for that patient, be sufficient to tip the scales in favour of taking the drug. Beverly Green is an example of a patient who had been offered tamoxifen before.

Beverly Green: The Cancer Centre's Record Management System

Ms. Beverly Green, a resident of St. John's, was diagnosed with breast cancer in February 2001. At the time of diagnosis, she understood that she was estrogen receptor negative and progesterone receptor strongly positive. This was the result of the tests on both her biopsy sample and her mastectomy sample. Ms. Green underwent a course of chemotherapy and radiation therapy.

After discussing possible treatments with her physicians and conducting her own research, she decided that, as she was ER negative, she would not take tamoxifen, although it was offered to her. She understood that the drug has side effects and that if she were not ER positive, it would be of limited benefit to her. A Progress Note by Dr. Farrell, dated November 29, 2001, states, "We offered the benefit of tamoxifen. We outlined to her the side effect profile... I also outlined to her th[e] benefits and the fact that she is not ER positive therefore the benefit case is not as strong as it would be if she had been."¹² Ms. Green's decision not to take tamoxifen at the time was influenced by her discussion with Dr. Farrell. Had she been told at the time that she was ER positive, her decision would have been different. On March 7, 2002, she was seen by Dr. Siddiqui. He also discussed with her the risks of taking tamoxifen but noted that usually the benefits are as great as the risks and she should probably give it a try.

Both Ms. Green's biopsy sample and mastectomy sample were re-tested. The result of the re-test on her mastectomy sample was that the

¹² Exhibit C-0008.

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ER went from negative to 20% positive. The PR remained positive at 70%. This result was placed as an addendum to her pathology report on October 20, 2005. She was still under the care of physicians at the Cancer Centre at this time. No one, however, brought the result of this re-test to her attention at that time. Her next visit to the Cancer Centre was on December 22, 2005. There was no discussion with her on this date of the re-test, and Dr. Siddiqui's Progress Note for that day still refers to Ms. Green as being ER negative and PR positive. Dr. Siddiqui testified that as he was aware the re-testing process was underway, he would check some patients' charts when they came to see him to determine whether they had in fact been re-tested. He also relied, however, on the re-test results being brought to his attention. He probably did not check Ms. Green's chart on this occasion to see if she had been re-tested. He conceded that it would have been easy to turn to the pathology section of her chart to check for an addendum. The plan was for her to be seen in six months by radiation oncologist Dr. Greenland, and to be seen again by Dr. Siddiqui in one year.

On February 3, 2006, the repeat on her biopsy specimen was entered on her chart. The result of that re-test was that Ms. Green had remained ER negative but her PR had converted from positive to negative. By March 26, 2006, this result had come to Dr. Siddiqui's attention. The practice was for the addenda to the pathology reports to be left in the treating physician's mailbox. Dr. Siddiqui wrote a notation on Ms. Green's chart as follows: "The ER/PR receptor re-staining done at Mount Sinai Hospital on February 3, 2006 entered in her chart showed that the ER and PR both are negative being 0%. She was previously described to be ER receptor negative but PR positive. However, she has refused tamoxifen so there is no change in the treatment for Beverly."¹³ This information was not conveyed, however, to Ms. Green at the time. Dr. Siddiqui testified that for patients for whom there was to be no change in treatment, it was his practice to inform them of the re-test results on their next visit. Of course Ms. Green's visits would alternate between Dr. Siddiqui and Dr. Greenland. Dr. Siddiqui does not recall

¹³ Exhibit C-0013.

speaking to Dr. Greenland to coordinate the communication to Ms. Green on her results.

Ms. Green's case was reviewed by the Panel and on May 8, 2006, Dr. Laing wrote Dr. Siddiqui a panel letter, which was copied to Dr. Robert Woodland, Ms. Green's family physician, and to Dr. Greenland. This letter refers to the re-test results from both the biopsy specimen and the mastectomy specimen. The letter concludes as follows:

Review of Ms. Green's medical chart revealed that her diagnosis was based on the results of the mastectomy specimen and she was offered treatment with tamoxifen which she refused. Therefore, the panel does not have any further treatment recommendations at this time.¹⁴

In reviewing Ms. Green's chart, the Panel should have had access to Dr. Farrell's Progress Note, in which he wrote that as she was not ER positive, the benefit of tamoxifen would not be as strong. In any event, it is difficult to understand why the Panel would base its recommendation upon a decision made by a patient when she believed she was ER negative. Further, by 2006 there were other treatment options available, so any concerns Ms. Green may have had about taking tamoxifen might have been addressed with a different drug. Dr. Siddiqui thought the Panel's recommendation was a reasonable one.

Ms. Green was seen by Dr. Greenland on May 26, 2006. The Progress Note of that date states that her pathology review has confirmed her to be ER/PR negative. It then contradicts that statement by saying she was initially PR positive. It also states that she declined tamoxifen at that time. Clearly, Dr. Greenland is referring to the re-test of the biopsy specimen. Ms. Green testified that there was no discussion regarding her re-test results during this visit. It appears the re-test of her mastectomy specimen, which had been entered on her chart some seven months earlier, had yet to come to the attention of her treating physicians. Nor had the panel letter come to Dr. Greenland's attention by this date. The panel letter was stamped "June 14, 2006," which, according to Dr. Siddiqui, would have been the earliest date that he could have received

¹⁴ Exhibit C-0014.

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the letter. This means it was almost another month from the time Dr. Laing wrote the panel letter until it arrived in her colleague's hands.

Dr. Siddiqui could offer no explanation as to why a re-test that had been done and entered on Ms. Green's chart on October 10, 2005, only came to his attention in June 2006. Before he testified in September 2008, he had not made any inquiries of anyone as to how that could have happened. The document is initialled by someone and stamp-dated October 31, 2005, indicating it was received on that date. There appears to have been no system in place in the Cancer Centre to confirm who was receiving patient information and that it had been brought to the appropriate physician's attention.

The delay in communicating with Ms. Green would not end there. While the panel letter had asked that the information be communicated to the patient as soon as possible, Dr. Siddiqui chose to wait for her next visit, November 17, 2006, some five months later.

By November 17, 2006, Ms. Green was noted to have lost some weight and had an ongoing cough. Dr. Siddiqui decided to follow up on this to ensure there was no "sinister pathology" responsible. The Progress Note for this visit refers to a discussion with Ms. Green regarding both her re-tests¹⁵. Ms. Green denied that this discussion took place on this date. Dr. Siddiqui testified that he would have to rely on the content of the note, as he would have no independent recollection of what was said on any given visit. He admitted that the statement, "I spoke with Beverly again in detail about her reviewed pathologies from her prior studies" is not an accurate statement. This was the first time, according to Dr. Siddiqui, that he had this discussion with her.

Ms. Green was next seen by Dr. Siddiqui on December 14, 2006. She did not receive good news that day. The scans had detected multiple lesions in her liver consistent with metastatic disease. She began another course of chemotherapy.

¹⁵ Exhibit C-0016.

Ms. Green contended that she learned of the change in her results only in April 2007. She had been speaking with a fellow breast cancer patient who told her everyone was being re-tested. She had not heard anything about her own situation, so at an appointment with Dr. Siddiqui on April 30, 2007, she asked for a copy of her chart. Ms. Green testified that his response was abrupt and out of character for Dr. Siddiqui. Dr. Siddiqui denied any such encounter with Ms. Green.

Ms. Green subsequently went to see Dr. Woodland, and he provided her with a copy of the May 8, 2006, panel letter. According to Ms. Green, this is the first time she learned of the change in her results. Ms. Green was not happy that the Panel, who were unfamiliar with her or her care to date, would have made any recommendation without consulting her. Further, she felt it was “unfair” that they would base their recommendation on the fact that she had refused tamoxifen at a time when she had been told she was ER negative.

On May 22, 2007, Ms. Green was seen by Dr. Siddiqui and she agreed to commence anti-hormonal therapy. She was offered Femara, instead of tamoxifen, for the first time. She testified that she was prepared at this time to take anti-hormonal therapy because she was now aware that her hormone receptor status was ER positive. This Progress Note and others on Ms. Green’s chart contain blanks where information is obviously missing. Quite a number of these Progress Notes are also “Dictated Not Read.” The importance of accuracy of the content of notes on a patient’s chart cannot be overemphasized: the accuracy of the notes ensures optimal continuity in the patient’s care, particularly when more than one physician is involved.

Ms. Green’s case demonstrates many weaknesses in the records management system of the Cancer Care Program. These issues need to be addressed to ensure treating physicians are receiving timely and accurate information about their patients. Appropriate mechanisms must also be put in place to confirm that the treating physician has received the information.

Ms. Green is one of the patients who developed metastatic disease between the time of her original diagnosis and the communication to her of the error in her hormone receptor status. She quite understandably feels the matter of communication of this issue was handled very poorly. In her words, it was “unprofessional” and “unforgivable.” She lamented the lack of disclosure to patients and opined that they had not been treated like adults who could be empowered to make their own decisions.

Delay caused by paneling

As it transpired, the process of being paneled caused delays in patients receiving results. This was particularly so for the DCIS patients and the retro-converter patients, as the Panel had difficulty deciding what to do with them. The circumstances of both of those groups are addressed elsewhere in this report. For some other patients, the delay can be attributed to the fact that additional information had to be obtained from other regional health authorities. There were also patients who were paneled in spite of the fact that they had already been seen by an oncologist and had their treatment adjusted in light of the re-test. Dr. McCarthy described such a situation, where she had taken the case to the regular tumour board rounds to seek the advice of her colleagues on appropriate treatment. Having such a person’s case reviewed by the Panel appears to have been an unnecessary step, particularly since there were many pending cases for which the Panel might have provided valuable assistance, and there was no effort to prioritize cases to be considered by the Panel.

After patients were panelled, those for whom there was a recommendation for a change in treatment were contacted as soon as possible and advised of that recommendation. However, where there was no recommendation for a treatment change for a Cancer Centre patient, Dr. Laing, Clinical Chief of the Cancer Care Program, advised the medical oncologists that the next scheduled clinic appointment for each patient would be an “adequate time” to advise them. Follow-up appointments were typically every six or twelve months. If Ms. Nancy Parsons received an inquiry from such a patient, she would not reveal the

results of the panel review. Consequently, such a patient could wait up to a year for the Panel decision. This decision seems to fly in the face of the reason Dr. Laing had given to Mr. Ottenheimer that if patients were aware of the re-testing process, waiting weeks would be too stressful for them.

In my opinion, the idea of a panel to provide assistance to general practitioners who would be faced with a most unusual circumstance in the treatment of cancer patients was a good one. As it turned out, 53% of the panel letters were sent to physicians at the Cancer Center or surgeons on the Panel. That is, over half of the patients whose cases were reviewed by the Panel already had access to the required expertise and if they needed further assistance it was readily available through the normal tumour board rounds.

Eastern Health's Policy on Disclosure

As already noted, Eastern Heath, and Healthcare before it, had a policy regarding disclosure of "occurrences" or "adverse events" to patients. That policy reflected certain basic principles, including the right of the patient to know "in a timely fashion" about adverse events. No one adverted to the policy in making the decisions regarding disclosure to patients. Some witnesses merely said that it obviously had no application because it was drafted for disclosure to one or perhaps a few patients and, therefore, it could be of no assistance in dealing with an event as large as this one. Ms. Predham stated that it was a "guideline" not a policy.¹⁶ As she explained it: "a guideline is a suggested route and that's what you typically would do in a situation. Of course, those guidelines were written for a situation involving one patient with a final outcome and you know, but this was part of a larger process."¹⁷ A suggestion by another witness was that, as those considering communications issues would have been aware of the policy, there was no need actually to consult it.

¹⁶ The policy applicable was entitled "Guidelines on Disclosure of Adverse Events," which no doubt created confusion regarding its status.

¹⁷ Transcript of testimony, Heather Predham, October 22, 2008, p. 78.

It is interesting to contrast the communications with the patients whose samples were re-tested before and after August 1, 2005. For example, the first patient to be re-tested, Ms. Peggy Deane, was told that the re-test was going to be done. When the changed results were received, she and her husband were told of the change by Ms. Deane's oncologists. It is not clear whether the four or five patients who were next tested were told before the re-test was done, but they were told by an oncologist of the changes in their results. The oncologist and the patient then had the opportunity to discuss possible changes in treatment. Most of the patients in the first group of 25 re-tested before the end of June 2005 by Dr. Carter and Dr. Cook were not advised that a re-test was to take place. The living patients whose results changed from clinically negative to positive were advised by a treating physician of the change. Where there was no change, the patients were not advised of the fact of the re-test at that time. After August 1, 2005, no further results from Dr. Carter's re-tests using the Ventana Benchmarks were communicated to the patients. Those patients who had been re-tested by Dr. Carter were re-tested again at Mount Sinai and the results communicated to them were those from Mount Sinai.

While I agree that because of the numbers involved with ER/PR re-testing it would not have been possible to comply strictly with the disclosure policy, I find it disturbing that instead of approaching the disclosure on the basis of adapting the policy to the circumstances, Eastern Health ignored the policy.

There exists, in my opinion disconnect between the approach of Eastern Health to the ER/PR problem and its position on disclosure. Witnesses employed by Eastern Health, notably Mr. Tilley, the former CEO, espouse the view that adverse events are system failures. They, of course, are not alone in that view. As the Canadian Disclosure Guidelines put it:

Many adverse events in healthcare are now recognized as system failures, where safeguards to protect patient safety were not in place, or a series of

safeguards that were in place failed in sequence, which resulted in harm to the patient.¹⁸

In the context of the disclosure, however, this notion seemed to cause a great deal of difficulty. For example, there seemed to be no difficulty in accepting that inadequate fixation was a contributing factor in the ER/PR problem. When considering what to say to patients, however, officials seemed reluctant to say anything unless they could be very precise. Some witnesses spoke of the need to isolate inadequate fixation as a causative factor in each case before that could be discussed with a patient. The search to isolate one cause seemed to fly in the face of the idea that a system failure is generally at the root of the error.

Communication with the Board of Trustees of Eastern Health

It is the responsibility of the CEO to communicate with the Board of Trustees. It is only to the CEO that the Board looks for information. The first notice of the ER/PR issue to the Board of Trustees of Eastern Health was in an email sent to Ms. Dawe, the Chair of the Board of Trustees, by the CEO, Mr. Tilley, on July 20, 2005. At 9:11 a.m., Mr. Tilley wrote:

Welcome back.

I will need to call you later today when I learn more but we potentially have a major clinical issue on our hands which pertains to the accuracy of laboratory testing for women who have been diagnosed with breast cancer, and get tested for the most appropriate treatment option. In 2004 we automated this procedure, so the issue pertains to testing pre 2004. The new process is said to be ten times more sensitive than the former, labour intensive, process. The issue was drawn to our attention when a lady who was originally tested in 2002 was retested in 2005 and found to have a positive result. Since we still had the specimens for those who were tested over the years (from St. John's) we have done some retesting of those done in 2002 and others have tested positive. The majority of the patients whose specimens we have retested and have converted to positive, have been in contact with their oncologist. The challenge now is to determine whether the new results are a consequence of the more sensitive technology we have acquired or an error in the way it was handled these tests in the past, and if it is the latter, whether it has been an ongoing problem or isolated to a particular year.

¹⁸ Exhibit P-0161, p. 12.

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I have been in touch with the Minister, who is edging us to go public asap. No doubt about the need to do that, but not until I know the size and shape of it. For example, late yesterday the size of the issue began to shrink as managers compared the results of these tests with national benchmark outcomes and found that in 2003 we were consistent. I am expecting a briefing [later] this morning when the results of this comparison are made for other years.

Bob Williams has been heavily involved and is providing great leadership to the follow up. I will keep you posted.

We will be briefing the Minister early tomorrow.¹⁹

Ms. Dawe promptly replied stating that she agreed “with making this public as soon as possible when you have the details” and asking for a briefing for the Board of Trustees before it was made public. Mr. Tilley’s knowledge of the Minister’s position was probably gained during his conversation with Mr. Ottenheimer on July 19, 2005. While Mr. Tilley describes the Minister’s position as wanting the matter made public as soon as possible, Mr. Ottenheimer’s position was, in fact, that there should be contact with the affected patients as quickly as possible. Mr. Ottenheimer was thinking of a letter as the means of communication. If that had been done, no doubt because of the numbers, it would have become public. Dr. Williams, on the other hand, thought initially that the only effective way of managing the disclosure was to go public as a means of initially communicating with the patients.

Of course, in the end, the matter was not made public by Eastern Health during the summer of 2005. The briefing of the Board of Trustees, therefore, took place during one of their regular meetings, held on September 21, 2005. Dr. Williams attended with Mr. Tilley and took the lead in briefing the Board. The minutes of that meeting contain the following:

Review of System - ER/PR testing for breast screening

There is an intensive investigation ongoing of the relative accuracies of two (2) systems used to detect estrogen and progesterone receptors in breast cancer tissue.

¹⁹ Exhibit P-0074.

Dr. Williams advised that the organization became aware of the situation in the spring. Conversion with the test results caused concern and subsequently resulted in the organization bringing in external expertise from the manufacturers of equipment, as well as a pathologist and a laboratory technologist with extensive knowledge in the area to provide an independent review of the system.

Patient safety and confidentiality are of paramount importance. The organization made a decision not to release any information publicly until the results of the retests were available. The Minister of Health and Community Services has been apprised of the situation. The organization is expecting additional information from Mount Sinai (the centre doing the retesting) during the coming days. The Board will be apprised as necessary.

Mr. Tilley's notes of that meeting indicate that Dr. Williams provided a history of ER/PR testing from the bioassay method to the "new technology" in 2004. He discussed margins of error and positivity rates, comparing those at Eastern Health to others. He reported that they had had a positivity rate of 73% since 1997 but, Mr. Tilley records, Dr. Williams added "though some years looked like potential problems." Dr. Williams also reported on the visits by Dr. Diponkar Banerjee and Ms. Trish Wegrynowski. Mr. Tilley's notes indicate that the Board was told of Dr. Banerjee's opinion regarding the sensitivity of the tests, and his view that the number of pathologists handling reading should be reduced and that all ER/PR tests should be read in St. John's. Dr. Banerjee was also reported to have opined that the stains he reviewed were comparable to those in other parts of Canada and superior to some. Ms. Wegrynowski was said to have commented on poor fixation of specimens. Mr. Tilley's notes may not have been complete. If his notes were complete, the summary Dr. Williams gave to the Board about the remarks of Dr. Banerjee was not a balanced one.

On September 30, Mr. Tilley advised members of the Board of Trustees that the issue was about to break in the media.

There were briefings for the Board of Trustees at other meetings. The ER/PR Re-testing Update in the minutes of the meeting of November 25, 2005, states:

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Dr. Williams provided an update on the ER/PR retesting as follows:

>- Dr. Williams and George Tilley met with the Minister of Health and Community Services, the Deputy Minister and their Communication Director on November 17th, 2005 to provide an update on the ER/PR Retesting.

>- We have been successful in making this a national issue. It is an agenda item for the Canadian Association of Pathologists and the Canadian Association of Oncologists at their upcoming meetings.

>- Reports are being prepared by the two external Consultants we invited to undertake an assessment. The reports will outline recommendations and a plan of action.

>- The organization has been in contact with Mount Sinai on a weekly basis with respect to expediting the retesting.

Of course, the reports of Dr. Banerjee and Ms. Wegrynowski had by November 9, 2005, been received by Eastern Health. Between the exit interviews with Dr. Banerjee and Ms. Wegrynowski and their reports, Dr. Williams had been made aware of many deficiencies in the immunohistochemistry laboratory.

On January 25, 2006, the Board was told that the recommendations from the reports had been identified. In a later report the Board was advised that technical review and follow up on recommendations were completed, as were the professional review and recommendations with follow up.

There is no indication that the Board of Trustees was ever made aware of the contents of these reports, nor was there any indication that the Board of Trustees ever sought information regarding the content of the reports of Dr. Banerjee and Ms. Wegrynowski.

The Board of Trustees played a passive role in ER/PR events. Some concern was expressed when there was adverse publicity concerning the matter, but essentially the Board of Trustees viewed ER/PR as an operations matter which should be left in the hands of the executive of Eastern Health. Indeed, the Board of Trustees continues to

feel that way. In submissions to this Commission, the Board has taken the position that:

Given the size of the organization and the extremely complex nature of health-care services, it is reasonable and prudent of the Board of Trustees to rely upon the advice and guidance of the professionals employed by Eastern Health with regards to the day-to-day management of the organization, all the while focusing its efforts on strategic planning, policy making, and accountability to the stakeholders.²⁰

Communication with the Public

It is generally accepted that there is no common law duty on Eastern Health to inform the public of large scale adverse events, though there may be occasions where public disclosure is required to meet the obligation to the patients. There may, however, be a statutory duty. Section 31 of the *Access to Information and Protection of Privacy Act*, SNL 2002, c. A-1.1, is applicable to the regional health authorities. Subsection (1) says:

Whether or not a request for access is made, the head of a public body shall, without delay, disclose to the public, to an affected group of people or to an applicant, information about a risk of significant harm to the environment or to the health or safety of the public or group of people, the disclosure of which is clearly in the public interest.

That having been said, communication with the public on such matters is a vital part of maintaining public confidence in the health care system.

In the end, Eastern Health lost control of when the ER/PR matter was made public. It was the October 2, 2005, *Independent* story that first made the ER/PR problem the subject of public discussion. Other media then followed the story. Media interest in the ER/PR story would wax and wane from October 2, 2005, onward, and Eastern Health continued to deal with the issue in a reactive rather than a proactive manner.

There was no plan within Eastern Health to deal with the ER/PR story if it broke in the media, though all involved, except Dr. Laing,

²⁰ Submission of Eastern Health, Conclusions, para. 21.

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anticipated that the story was going to break. As noted earlier, it was Dr. Laing who reluctantly gave an interview for the *Independent* story. The reporter concluded that it was new information regarding hormone receptor tests that led to the decision to do the re-testing and that the number of patients expected to be affected would be small. Dr. Laing was quoted as saying: “so it’s not a huge thing.”

In Eastern Health’s first public communications on the ER/PR issue, the cause of the inconsistency in results was attributed to new technology. Ms. Bonnell was noted in the breaking story of October 2, 2005, to have said a new, more accurate piece of equipment was installed in the laboratory last year, providing clearer results. An article in the *Telegram* on October 5, 2005, notes that the reason for the discrepancy in results isn’t clear but the previous year Eastern Health had implemented a new fully automated system. Dr. Williams is reported to have said the older system was semi-automated and the testing involved multiple steps.²¹ On October 13, 2005, NTV reported, “There was no mistake. New sophisticated technology became available and produced more accurate results.” Surprisingly, Eastern Health’s communication personnel, in analyzing the story, took exception only with the word “accurate,” stating that the reporter should have said the technology is more “sensitive.”²² Eastern Health was minimizing the extent of the problem and leaving an erroneous impression as to its cause.

In October 2005 Eastern Health posted answers to Frequently Asked Questions on its website in a further effort to communicate information on the issue. The answers convey the same message that was being reflected in the media about the size of and reason for the problem. The answer given to the question, “I haven’t been contacted, what should I do?” suggests patients could contact their physicians and as well, the contact information for Eastern Health’s Patient Relations Officer is given. Unfortunately, however, the answer begins with the statement that “...patients are being contacted if there is a change to their result and their treatment may be affected.” Patients reading this could

²¹ Exhibit P-1662; Also: CBC News story, October 5, 2005, Exhibit P- 3153.

²² Exhibit P-0642.

reasonably interpret it to mean that this problem only affects a small number of people and if they have not been contacted, they are not involved. Later, the decision was made to telephone patients who were being re-tested, but not everyone could be contacted. This highlights the importance of accuracy in public messaging, to ensure nobody is overlooked or lulled into a false sense of security.

Mr. Tilley was not interested in being a spokesperson for Eastern Health on this issue. He was of the view that Eastern Health had a poor relationship with the media. While there were occasions when Strategic Communications argued Eastern Health should be proactive, the general attitude was that keeping the story in the public forum was detrimental to Eastern Health's best interest. For example, on October 6, 2005, Mr. Peter Dawe brought to Mr. Tilley's attention that there was an inaccuracy in a CBC news story in that it suggested the problem was with false diagnosis of cancer. Eventually, largely through the efforts of Ms. Stokes-Sullivan, the story was corrected. Ms. Bonnell's initial response, although she thought the story was "problematic," was that she did not think it was worthwhile seeking a retraction, as the more "we drag this out, the worse it is for us."²³ By October 25, 2005, Ms. Pennell was trying to stop Eastern Health from carrying out any further interviews on the issue "so it would die."²⁴ I would add that there were similar comments within Government. In an email dated October 3, 2005, to Mr. Ottenheimer, Mr. John Abbott, and Ms. Hennessey, Ms. Tansy Mundon outlined why a news release would not be warranted at that time: "If we did issue a news release at this point, it would be picked up by local newspapers and would probably draw attention to the issue unnecessarily."

After the initial efforts to communicate its key messages, in the fall of 2005, with Dr. Laing and Dr. Williams as the spokespersons, unhappy with the way the story was being told, Eastern Health largely withdrew from public comment. In August 2006, Mr. Tilley's written statement was read on the *Current*, as already noted. The messages reflected those conveyed in the fall of 2005.

²³ Exhibit P-0348.

²⁴ Exhibit P-1532.

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Later in 2006, Eastern Health succumbed to media and public pressure and conducted a briefing for the media and others. The media technical briefing has been described elsewhere in this report. Following the media briefings, the ER/PR issue does not become prominent again in the media until reporter Mr. Mark Quinn's story on May 15, 2007. That same day, as a result of Mr. Quinn's story, the issue was raised for the first time in the House of Assembly and for the first time since the issue arose two years previously, Government spoke on it publicly.

Mr. Ottenheimer testified that during his time as Minister he went to the House of Assembly each day prepared with briefing notes to speak to the issue but no question was ever put to him. He did not take the initiative to address the matter without a question being put to him, nor did his successor, Mr. Tom Osborne. On May 15, 2007, Minister Ross Wiseman, in answering questions in the legislature, described the current system as a "Centre of Excellence," stating that very stringent requirements had been put in place, including additional training for the technologists and the pathologists working in the area.²⁵ He also stated that he wanted to provide comfort to the people of the province that the tests that they are getting done today had been subjected to a very rigorous quality assurance program. He was not aware at the time that ER/PR testing had not resumed within the province for patients outside Eastern Health. Nor was he apparently aware that pathologists outside Eastern Health still did not know about the problems with fixation that had been identified through the external reviews in 2005. In answering a question put to him as to what had been put in place to ensure patients in the future receive direct information and do not have to learn about such issues through the media, Mr. Wiseman responded that inherent in the quality control program that he had outlined were mechanisms to ensure appropriate reporting takes place. It is unclear what he was referring to. Later that day, in a media scrum, Mr. Wiseman was quoted as saying he understood Eastern Health's dilemma in trying to balance their responsibility to the patients and their responsibility in protecting the interests of the organization in the event of litigation.²⁶

²⁵ Exhibit P-0105.

²⁶ Exhibit P-0438.

Over the course of the next week, Mr. Wiseman repeatedly offered assurances to the people of the province as to the quality of the service now available. Perhaps more unfortunately, he continually maintained that all the patients had been contacted. This proved not to be the case. In fact, not all patients had yet even been identified. Mr. Wiseman also made other erroneous statements, which leads one to speculate as to how well he was informed. For example, Mr. Wiseman stated in the House of Assembly that Eastern Health, in making its initial decision to hold off on informing people about the re-tests, was following the advice of a subcommittee of its Ethics Committee, which consisted of people from the community, physicians, and others who are experts in this field.²⁷ Further, Mr. Wiseman is quoted as saying that at no time was there a risk to the 200 patients who had a change in results but did not require a change in treatment.²⁸ Included, however, in that number would have been patients who did not require a change in treatment because they had already been prescribed anti-hormone treatment for metastatic disease. Some of these patients had in fact faced significant risk. At a time when much confusion already existed in the public on this issue, one would expect it would be reasonable for the Minister to ensure the accuracy of his information before speaking publicly.

Meanwhile, on May 15, 16, and 17, 2007, Eastern Health meanwhile continued to choose not to speak publicly, despite requests for interviews from both local and national media outlets. Its attitude towards the media remained reactive and defensive. On May 16, 2007, Ms. Predham in an email internal to Eastern Health expressed concern that to say anything publicly would only “give them more fodder and that whatever we say, we’ll fan the fires...it would be better to hold the no comment line.”²⁹ The same day, Ms. Bonnell emailed Mr. Tilley, Dr. Oscar Howell, and Mr. Stephen Dodge, outlining why Eastern Health should speak publicly. She wrote: “Our credibility as an organization and our ability to provide quality care are being maligned,” and she warned

²⁷ Exhibit P-0105, p. 21, Hansard, May 23, 2007,.

²⁸ Exhibit P-0105, p. 7, Hansard, May 16, 2007.

²⁹ Exhibit P-0106.

that if Eastern Health did not speak, the public would automatically assume there is something to the allegations.³⁰

On May 18, 2007, at the direction of Cabinet, a press conference was held by Eastern Health at which Mr. Tilley spoke. He began by saying his purpose was to clarify “misinformation” about ER/PR testing that had been in the public the past week. He apologized for the confusion that had ensued over the issue. He also stated that it was “important for everyone to know that we contacted each and every patient who was affected by the ER/PR test review, making sure they received all the information and support they required.”³¹ When asked by a reporter how he could explain the magnitude of the errors, he responded by referring to an element of uncertainty in the test and that an independent physician had stated that Eastern Health’s laboratory was in “the middle of the pack.” He said that the individuals doing the independent assessment were not able to point to a technique, a person, or a discipline that had done anything that would suggest that errors would occur.³² Mr. Tilley made similar comments in an interview with NTV.³³ When one reads the reports of Dr. Banerjee and Ms. Wegrynowski and the more than 50 recommendations contained in their reviews, it is difficult to reconcile Mr. Tilley’s public comments with the reality of the situation.

On May 22, 2007, the government publicly announced this Commission of Inquiry. In the background information provided with the press release announcing the Inquiry, the government continued to

³⁰ Exhibit P-0012.

³¹ Exhibit P-0443.

³² Exhibit P-0206, p. 15.

³³ Exhibit P-0206, p. 22; “I have a superb team of professionals working in Eastern Health. They’re very committed. They’re very well trained. When we looked at this system we looked at other centres of excellence in Canada and we have taken all of the insights that we’ve learned from them to further improve upon the service that we have. We did have an opinion from an outside physician who said that Eastern Health programs for ER and PR testing probably fits somewhere in the middle of the pack in the ... country. But we’re not satisfied with people in the middle of the pack. We want to be on the top of the pack. So we’ve made every effort to put the measures in place to ensure that we have ourselves achieved a standard of excellence”.

state publicly that Eastern Health had contacted all patients who were affected by the ER/PR test review, or their family physicians, to make sure they received all the information and support they required, and that there had been full disclosure to patients and their families once test results became available.³⁴

It was not until Mr. Robert Thompson did an analysis of the material and pressed the point in June 2007 that Government finally questioned whether all patients had indeed been contacted.

Communication with Other Regional Health Authorities

Generally speaking, the ER/PR problem was managed by Eastern Health. Pathologists with other regional health authorities followed the directives of Dr. Cook or Dr. Carter regarding sending blocks for re-testing. The first request from Dr. Cook was contained in his letter of June 14, 2005. It asked that all negative ER/PR cases for 2002 be sent to the General Hospital laboratory. That request was not seen as significant by the pathologists from the other regional health authorities. Generally, they thought they were cooperating in some quality initiative by Eastern Health. When, later in the summer, Dr. Cook called to tell them that he would be sending a request for many more blocks covering a much longer period of time, they began to realize that the issue was an important one, potentially affecting patient care.

Dr. Ken Jenkins, the Medical Director of Western Regional Integrated Health Authority, stated that he first heard of the ER/PR issue during a medical directors' meeting on September 29, 2005, when the issue was raised by Dr. Williams. That same day, Ms. Predham wrote to her counterparts³⁵ in Western Health and Central Health, giving them some background related to the problem and telling them that she wanted to give them a heads-up "as we have to begin to inform people individually about this issue." This email was sent within days of the first of the re-test results having being received from Mount Sinai. It is apparent from the correspondence that Ms. Predham was assuming that

³⁴ Exhibit P-0213.

³⁵ Ms. Susan Sullivan of Western Health and Ms. Judy Budgell of Central Health.

the other risk managers were not aware of the problem.³⁶ She said: “the Department of Health wants us to make a public statement. Since your labs have not responded yet to our request I may be asked about the reason why. What do you think?”³⁷

Dr. Alteen, the Medical Director, Central Regional Integrated Health Authority, remembered that he was first told about the issue by Dr. Maurice Dalton, a pathologist within his own organization. Dr. Alteen’s next memory of the ER/PR problem is of late September 2005, when Central Health was advised that the story was about to break in the media. Dr. Alteen advised his then CEO, Mr. David Diamond.

On September 30, 2005, Ms. Predham contacted Ms. Susan Sullivan again, this time by telephone. Ms. Predham advised Ms. Sullivan that the issue was about to hit the media,³⁸ and that Mr. Tilley would be in touch with the other CEOs on the subject. Within Western Health, Ms. Sullivan passed the message to the CEO and Dr. Jenkins. Dr. Jenkins recognized that this might be a particularly “sensitive and complicated issue to communicate.” He looked to have Dr. Paul Neil, Director of Pathology, provide information to others in the organization.

On October 3, 2005, Ms. Bonnell, in a telephone conversation, provided Dr. Alteen with a general summary of what had occurred since the story broke the day before and of Eastern Health’s plans. This included the information that Eastern Health would not be doing a press release but would be posting Frequently Asked Questions on its website.

On October 4, 2005, there was a conference call involving other regional health authorities. Chief Executive Officers and/or Vice-Presidents, Medical Services, participated. Dr. Cook recalled this discussion to have been about the practical issue of how the Mount Sinai results would be entered in patients’ charts. During the teleconference, he

³⁶ Exhibit P-2352.

³⁷ In fact, Grand Falls had already sent all of its blocks to St. John’s, as had Gander.

³⁸ Eastern Health had received inquiries from two different media outlets on September 30.

also advised them about the letter to surgeons that was being drafted within the Cancer Centre. Dr. Alteen's notes of the call indicate that many topics were covered and suggest a somewhat detailed briefing was provided. Dr. Williams' notes record that during that conference call the question was raised as to whether all patients being re-tested should be notified.

In Western Health, on October 4, 2005, Dr. Jenkins distributed questions and answers to physicians and nursing administrators, public health nurses, and others to help them answer questions patients might ask about ER/PR. There was also a handout provided. In doing this, Dr. Jenkins was taking a different approach than Eastern Health had taken. Dr. Jenkins was obviously anticipating that many of Western Health's employees would be asked questions about ER/PR. He chose a course of action that put them in a position to respond, albeit without much detail. Dr. Michael Jong, VP, Medical Affairs, Labrador-Grenfell Regional Integrated Health Authority, took a similar approach by distributing a handout to provide to patients who might have concerns about the issue. While I applaud those efforts to provide information, unfortunately reliance was placed on information provided by Eastern Health, which was, at best, misleading.

Eastern Health had chosen to limit the number of people who were dealing with ER/PR issues and directed all general inquiries to one place, the Quality Department. This meant that the Quality Department staff and the oncologists were the only people within Eastern Health who were in a position to answer patient's questions about ER/PR re-testing. Neither the oncologists nor the Quality Department staff answered questions about the cause of the problem, other than to speak of there being an ongoing investigation or the problem being complicated or the cause being unclear.

In the meantime, Ms. Stephanie Power, Director of Communications and Planning, Central Health, prepared a draft briefing note for Dr. Alteen and Mr. Diamond in anticipation of a communication with "stakeholders" about the issue. In it she concentrated primarily on Central Health's activity related to ER/PR re-testing.

Hormone Receptor Testing

On October 11, there was a conference call in which Ms. Pat Pilgrim, Ms. Predham, Dr. Williams, and Mr. Tilley participated from Eastern Health; Mr. Dave Diamond, Ms. Betty Forward, and Dr. Alteen represented Central Health and Dr. Jenkins, Western Health. The representatives from Eastern Health provided an update. Eastern Health indicated it was agreeable to other regional health authorities referring their patients to the feedback phone line staffed by Eastern Health's Quality Department staff. Dr. Williams advised that any decisions on treatment would be made on an individual basis. Eastern Health also advised that they would keep a global registry. Dr. Alteen's notes concerning Mr. Tilley's remarks indicate that: each region would identify a person to contact on the issue, those people would decide on the frequency of conference calls required, and Eastern Health's website and consumer line should be used by all as a point of contact.

Much communication took place between officials of Eastern Health and those of Central Health and Western Health from the end of September to mid-October, 2005. I have not specifically mentioned all of them. The conversations included information regarding the discovery and management of the problem by Eastern Health and provided Central Health and Western Health with information to deal with inquiries from patients and others. There was then a lull in communications between Eastern Health and the other regional health authorities on the subject of the ER/PR problem, until the results of the re-tests for those regions began to be processed by Eastern Health, beginning in late January 2006.

On February 21 and 22, 2006, emails were exchanged between Ms. Predham and Ms. Judy Budgell, with copies to Ms. Sherry Freake. Ms. Budgell was the risk manager in Grand Falls; Ms. Freake held that position in Gander. Both work for Central Health. Ms. Predham sent Ms. Budgell the results for blocks originating at the hospital in Grand Falls and asked for further information on some of the patients. She added that the Panel would be meeting that Thursday to start the Gander cases. Ms. Budgell replied with a question about what would now happen to the patients who had been paneled where there was a recommendation for treatment change. Ms. Predham explained that a letter would be written

to the most responsible physician and copied to others listed on the chart, as well as to the Grand Falls peripheral clinic. She also said that within a couple of weeks, she and Ms. Nancy Parsons would be calling physicians who had been sent a panel letter to verify that it had been received and the patient informed.³⁹ In the end, the contacts with patients who had been re-tested were handled in the same way for the entire province, except for those who were confirmed negative. Where the specimen came from a Central Health hospital, Central Health would make the phone call to the patients to advise them of the results of the re-tests. Similarly, Western Health made the calls to their patients. Eastern Health made the calls for Labrador-Grenfell Health.

On November 21, 2006, Ms. Freake, the regional risk manager from Gander, emailed Ms. Predham, asking what was happening regarding the deceased, the retro-converters, and certain other patients. She reported that most of the other patients in the Gander region had been contacted about their re-test results. On December 5, 2006, she was still looking for answers to her questions of November 21, 2006.

By March 2006, attention had turned to Western Health's patients. Ms. Predham provided similar information to Western Health as had been provided to Central Health. She undertook to send to Western Health the script that Eastern Health had used in its contacts with the confirmed negative patients and explained how the Panel worked and who communicated with the patients who had been paneled. Dr. Alteen also noted that "deceased will be reviewed and panel deceased converted patients."⁴⁰ Ms. Predham sent the script on March 22, 2006. She noted that they did not leave messages or voice mail, and that they called on weekends and during the evenings to ensure they made contact. As the message used by Eastern Health had done, it said: "We are pleased to tell you that we have your results back and there is no change from what they were originally. Everything remained the same for you"

The suggested answer in the script to the question "how did this happen?" was:

³⁹ This was not done, at least not before 2008.

⁴⁰ Exhibit P-2924.

Commission of Inquiry on
Hormone Receptor Testing

Due to the discovery of inconsistent results, Eastern Health has begun retesting breast cancer patients whose results indicated that they were negative for estrogen receptors. As the results of the test influence[s] treatment, we felt it was important to make sure all the test results were accurate. That is why we are retesting all people who tested negative for ER from 1997 to August 2005.⁴¹

The suggested response did not address the question.

Dr. Alteen, who had, by March 22, 2006, been party to a number of conference calls and communications in other forms, still believed that no one knew what had happened and why. He had some vague notion of the problem being attributable to the older DAKO system.

The feature of the communications between Eastern Health and the other regional authorities that raises concern is the failure to communicate vital information regarding the ER/PR testing process. On January 20, 2006, Dr. Brendan Mullen, of Mount Sinai, sent Dr. Cook what he then thought was the last of the re-test results. He added:

When you have had an opportunity to review the results, I would like to discuss some of the technical difficulties we encountered with processing and staining the specimens. Some of the same issues are present in the current NL material.⁴²

In his testimony, Dr. Cook said that he had no recollection of discussing this with pathologists in the other regions. Dr. Alteen testified that he had never been advised of this communication. As a result of the visits of Dr. Banerjee and Ms. Wegrynowski, Eastern Health was aware before the end of 2005 that there had been historic problems with fixation and tissue processing. In fact, by the end of July 2005, Eastern Health was aware of the observations of Dr. Carter and Dr. Cook of problems with tissue fixation and processing and with the interpretation of slides. On November 20, 2006, Dr. Ford Elms during a video conference with pathologists, including those from other regional health authorities, gave a presentation on the subject of immunohistochemistry. The subject of

⁴¹ Exhibit P-2849.

⁴² Exhibit P-1711.

fixation was part of that discussion, which was generic and not directed to what had happened in the past. If it was intended to convey a message that the other regional health authority laboratories had had fixation problems from 1997 to November 2006, it did not do so.

Eastern Health's approach to the issue is best illustrated by an excerpt from the minutes of an Executive Management Committee meeting of November 21, 2006, during which presentations were made:

The following points were raised during the presentation:

The organization cannot speak publicly on the findings and recommendations of the Review because there is currently a class action law suit ongoing. This information is protected under the evidence act. Discussion ensued regarding the need to share the experience with the other pathologists within the province. *Dr. Howell and Dan Boone to discuss further prior to making any discussion [sic] to discuss the Reviewers report with the provincial pathologists.*⁴³

Mr. Boone, who attended the November 21, 2006, meeting, testified that he did not recall any discussions with Dr. Howell about the question. I shall return to the questions of peer review protection and s. 8.1 of the *Evidence Act*, RSNL1990, c. E-16 later in this report. At this point, I merely highlight the obvious: a year and a half after the ER/PR problem was recognized, a year after the reports of Dr. Banerjee and Ms. Wegrynowski were received by Eastern Health, and more than 10 months after Dr. Mullen's comment to Dr. Cook regarding fixation, the other regional health authorities had not been provided with information respecting potential deficiencies in their work.⁴⁴

⁴³ Exhibit P-2108.

⁴⁴ During the October 4, 2005, conference call with CEOs and VP medical, in which pathologists from the regions did not participate, the regions were advised that there was a need to ensure collection and preparation of specimens were done in a standard procedure across the province and this would include the standardizing of formalin. This general statement could not be said to be proper notification to the other regional health authorities of problems with fixation and processing of specimens from the regional laboratories.

The issue of fixation was to arise, however, in a conference call held on May 24, 2007, between officials of the Department of Health and Community Services and representatives of the four regional health authorities. The reason for the call was that when re-testing for ER/PR had resumed in St John's in February 2007, Government had assumed that testing for the entire province was, from February, being done at Eastern Health. That had been revealed not to be the case, and officials of the Department were inquiring about the matter. Dr. Alteen's notes of the May 24, 2007, conversation attribute to Dr. Nebojsa Denic and Mr. Gulliver the information that Mount Sinai would like St. John's to take over ER/PR testing for the entire province and the suggestion that reading of the ER/PR slides in future be done in St. John's.⁴⁵ Dr. Denic is recorded as having added that there was a need to ensure that the fixation process for preparation of samples is at the same standard across the province. To that end, Eastern Health had prepared a document designed to ensure that each region understood and complied with Eastern Health's fixation protocol when ER/PR testing was resumed at Eastern Health for the entire province. Dr. Alteen also noted that Dr. Dalton remarked that this was the first he had heard of a fixation problem,⁴⁶ and Dr. Alteen asked why they had not been told about it before. Dr. Denic is recorded as having said that during the review process, fixation had been identified as a problem in all regions. So then, two years after the problem arose and over a year and a half after the external reviews, the other regional health authorities first learned of a problem with potential ramifications for the validity of the tests they were performing. They were, of course, hearing only part of the story.

The ER/PR problem was not confined to the IHC section of the clinical laboratory at the General Hospital. It involved the handling of the specimen from its removal from the patient to the reading of the ER/PR slide. That was true whether the patient's surgery was in an Eastern Health hospital or one operated by another regional health authority.

⁴⁵ The idea of a small group of pathologists reading the tests related to breast disease had been raised in the conference call of October 4, but at that point it was said to be something that Dr. Banerjee would be recommending in his report.

⁴⁶ Dr. Alteen told the Inquiry he believed that just prior to this, Dr. Dalton had heard informally that there had been a fixation problem.

Fixation in Corner Brook or Labrador City was just as important as fixation in St. John's. Therefore, any observations or opinions expressed by Dr. Banerjee or Dr. Mullen (or Dr. Carter) regarding those aspects of specimen handling which occurred before the staining of the slides in the IHC section of the laboratory in St. John's were equally important to the other regional health authorities. Whether Eastern Health acted in this regard on the basis that they were performing a service for another health organization or for individual patients, it was, in my opinion, unconscionable to wait until Eastern Health was offering to provide ER/PR service again to tell the other regional health authorities about the problems identified in the pre-analytical stage of ER/PR testing. That information should have been communicated immediately. Fixation was important to ER/PR testing whether the staining of the slides was being done in St. John's or Toronto. Further, fixation is not important just for ER/PR testing. Eastern Health cannot be permitted to cite a practice such as peer review protection as a justification for failing to take action to protect the safety of patients of other regional health authorities.

Communication with Government

Eastern Health accepted that it had an obligation to tell the Minister about the ER/PR problem. It generally did not provide written information to the government regarding the ER/PR problem unless the government requested it or the circumstances were such that Eastern Health could be confident that such a request would come, such as when Eastern Health learned that there was to be a story in the *Independent*.

There was, however, an informal arrangement between the people in communications within Eastern Health and those in similar positions within the Department of Health and Community Services. As a matter of courtesy, one would generally advise the other, in advance, of any public announcements that could be said to be of mutual interest. In that context, it would not be unusual for Ms. Carolyn Chaplin or Ms. Tansy Mundon to receive a call advising that Eastern Health would be making a significant announcement in a few days, or for Ms. Bonnell to receive a similar call from the Director of Communications within the Department.

None of the witnesses who were asked were able to articulate clearly what the relationship was between the Department of Health and Community Services and the regional authorities. Mr. Abbott's view was that there was no relationship between the two. Rather, it was the Minister who had the relationship with the regional health authorities and from time to time the Department, or he, as Deputy Minister, was asked to take action to assist the Minister with his duties. That clearly does not reflect the Government view as it is expressed in the submission to this Commission, nor was it consistent with Ms. Hennessey's understanding of the Department's role. Ms. Hennessey's duties as Assistant Deputy Minister, Board Services, required her to have regular contact with the regional health authorities. I accept Ms. Hennessey's evidence that when it came to matters relating to Eastern Health, "for the most part Mr. Abbott took a leadership role himself on the files." She also noted that, in respect of the ER/PR file, much of the contact was directly between Mr. Tilley and Mr. Abbott. We know little of what occurred during those exchanges, as there was little written record of their discussions.

In the decision not to advise the patients prior to the return of the results, Dr. Laing's opinion was all-important. If she cannot be said to have converted the Minister of Health and Community Services to her view, she was persuasive enough that he no longer pushed for immediate disclosure to patients that there was to be re-testing. Dr. Williams, who maintained that he always favoured early disclosure to the patients, did not argue against her position, whatever he believed. It seemed that no one took issue with Dr. Laing's position, except perhaps Mr. Hynes, but that came later and was in respect of the re-test of the specimens of the deceased.

The Role of Other Stakeholders

Newfoundland and Labrador Medical Association

The Newfoundland and Labrador Medical Association had little involvement in communications related to the ER/PR problem. It co-operated with Eastern Health in facilitating communication with

physicians throughout the province. In my opinion, more should and could have been done to provide physicians, who were likely to be faced with questions from their patients, with information to assist in answering those questions.

Canadian Cancer Society, Newfoundland and Labrador Division

Mr. Peter Dawe is the Executive Director, Canadian Cancer Society, Newfoundland and Labrador Division. He is an articulate advocate for cancer patients. As advocates do, from time to time he disagrees with the policies or positions of the very people he is trying to convince to take a particular course of action. He explained, however, that his role was not just as an advocate but also to assist, where he could, in policy development. Mr. Dawe's view was that from 2005 through 2007 he had a healthy working relationship with the Government, though he acknowledged that it was not always an easy relationship. He believed that the key to keeping the relationship healthy was good communication. Mr. Dawe did not think his relationship with Eastern Health was as healthy. He identified the problems as arising, in particular, out of public advocacy. In other words, Eastern Health did not take kindly to adverse public comment. On the evidence before the Commission, I would agree with Mr. Dawe's observation.

After the ER/PR story broke, in Department of Health and Community Services' briefing notes, it was not uncommon to see references to the position taken by Mr. Dawe. The November 7, 2005, briefing note for the Department of Health and Community Services⁴⁷ quotes Mr. Dawe as having said: "There is absolutely no doubt that there is a group of women out there that didn't get proper treatment and that could have very dire consequences." In December, the then parliamentary secretary to the Minister of Health and Community Services was being advised that Mr. Dawe had said that the wait for results could have been shorter. Though Mr. Dawe's comments related to Eastern Health, not the Government, it is clear that his statements were not favourably received by all.

⁴⁷ Exhibit P-0124.

Hormone Receptor Testing

Early in 2006, Mr. Wiseman, then the Parliamentary Secretary for the Minister of Health and Community Services, and later Mr. Abbott, the Deputy Minister, on separate occasions spoke to Mr. Dawe. Mr. Wiseman suggested to Mr. Dawe that he was being too aggressive in his remarks about ER/PR and that he should back off. Mr. Wiseman made the point that Mr. Dawe's comments made working with the Cancer Society difficult and that Mr. Dawe did not have to deal with all issues in the media. As Mr. Dawe put it, he and Mr. Wiseman agreed to disagree on the subject. The conversation with Mr. Abbott contained the same message but, as Mr. Dawe saw it, Mr. Abbott was blunter. Mr. Abbott effectively told Mr. Dawe that his having said that someone could have actually died from this was over the top, or too drastic a statement. Mr. Abbott recalled that he advised Mr. Dawe that his adverse comments were undermining the Minister's efforts when he was seeking support for cancer initiatives. About a week later, Mr. Dawe had a meeting with the Minister, Mr. Ottenheimer, in which a similar message was delivered but there was no reference to ER/PR. That time, his comments regarding another cancer care issue were referred to as causing difficulties. Mr. Dawe agrees that following that conversation Government participated in a number of cancer initiatives. Mr. Dawe's public comments continued to appear in Departmental briefing notes.

The evidence regarding the relationship between Mr. Dawe and government ministers and officials leads me to accept Mr. Dawe's assessment. The government clearly did not like the negative comments, though they were directed toward Eastern Health. However, there was greater understanding of and acceptance of Mr. Dawe's duty as Executive Director of the Cancer Society within Government than within Eastern Health.

After the story broke, Mr. Dawe gave interviews regarding the issue. He also monitored how the story was being portrayed by the media. For example, on October 6, 2005, Mr. Dawe advised Mr. Tilley

about the CBC online story⁴⁸ that had suggested the testing was diagnostic. His clear intent was to ensure that there was no misinformation about the ER/PR issue.

However, by October 19, 2005, just a couple of weeks later, Mr. Tilley suggested to Ms. Chaplin that Eastern Health's briefings of Mr. Dawe had been of no benefit, in light of his comments in the media. Mr. Tilley acknowledged to Ms. Chaplin that he was being over-sensitive. However, the message seemed to get to Mr. Dawe, perhaps through Dr. Williams, with whom he had the most contact. On October 20, 2005, Mr. Dawe emailed Ms. Bonnell, with a copy to Mr. Tilley and Dr. Williams, to express approval of Eastern Health's decision to contact all of those who were being re-tested. He also explained that an interview aired the night before (Wednesday) had been taped on Monday morning and made the point that his comments had been "reflective of the feedback [he was] receiving from the public."⁴⁹

On August 8, 2006, Dr. Williams was on holiday. Ms. Pilgrim was filling in for him. She was preparing to update Mr. Dawe. She sought the advice of Ms. Bonnell and Ms. Predham about whether and, if so, how to do this, as Mr. Dawe was on holiday. She also wanted to know what she should include of the information she had listed. Ms. Pilgrim noted that 1069 cases had been reviewed by Mount Sinai, that the "vast majority" of the patients had been notified, and that Eastern Health was in the process of contacting physicians who had been communicating with patients to confirm that the patients had been contacted. She briefly explained the role of the Panel. She acknowledged that as part of the review they had found a "small number" of patients who required further follow up, not on ER/PR but on issues detected during the review. Ms. Pilgrim added: "As you know, any review of this magnitude will result in identification of issues that we might not have been otherwise aware of." Ms. Pilgrim expresses the hope that the review and follow up with patients would be completed by the end of summer and then they could turn to analysis

⁴⁸ That was the story by Ms. Stokes-Sullivan for the *Telegram*, which had been re-written for CBC's website and which misinterpreted the situation. It was eventually corrected through the efforts of Ms. Stokes-Sullivan.

⁴⁹ Exhibit P-1497.

and summarizing the results of the review, and any changes they have implemented, or planned to implement, as a result. She ends by stating the commitment to disclosure and attention to the needs of the patients.

Ms. Bonnell suggested that rather than send the information, Ms. Pilgrim email Mr. Dawe and advise him that there have been developments and he can get in touch if he has questions. "Put the ball back in his court ... I think the offer to keep him in the loop is as important if not more important than the actual information you can provide."

In November 2006, just before the media technical briefing, it was the Department that insisted that Mr. Dawe should be given a briefing before the media briefing. I accept the evidence of Mr. Hynes that Eastern Health was reluctant to do this. On November 27, 2006, Ms. Mundon was checking with Ms. Bonnell to see if the briefing for Mr. Dawe had been set. Ms. Bonnell replied to the effect that they would try to fit him in on the same day as the media briefing, December 11, 2006, but she was not sure if they would be able to. She added "He won't be getting the advance 'good-will' presentation I offered him last week ...you [throw] someone an olive branch and they whip you to death with it fool me once." Ms. Bonnell explained that there was a fear that Mr. Dawe would give the information to the media if he was given an advance briefing. While Ms. Bonnell expressed embarrassment at the language she had used, she did not, though questioned on the point, provide an explanation for her statement. I am unable to explain the reason for this remark.

Following the media briefing, Mr. Dawe was quoted in a CBC story again. Once again he was describing not receiving treatment as potentially "meaning a life and death issue for people going through the process." He was also quoted as saying "lack of disclosure raises questions about what the problem is and how it can be fixed." In the Department of Health and Community Services, Mr. Hynes and Ms. Mundon were agreeing that Mr. Dawe had a point. By May 2007, Ms. Bonnell was trying to get officials of Eastern Health to speak publicly on the issue. One of her arguments was that if they do not speak, the media

look for less credible spokespeople who will speak to them. “Hence, Peter Dawe, Gerry Rogers, Ches Crosbie.” Later in the memo she says that they are allowing the Canadian Cancer Society to leave the general public with the impression that there is a new group of women. “This is causing confusion and we are getting calls asking about this. There’s a new level of fear and anxiety that Peter Dawe is creating and then blaming us for.” Ms. Bonnell acknowledged that her statement of Mr. Dawe was untrue.

The unfortunate part of the strained relationship between Mr. Dawe and Eastern Health is that opportunities to use the Canadian Cancer Society to assist in dealing with the problem were lost. With the exception of one unsuccessful effort in 2008 to arrange a TV program in which both Mr. Dawe and representatives of Eastern Health would appear, there seems to have been little effort by Eastern Health to use the Canadian Cancer Society as a vehicle to communicate with patients or to elicit the views of patients regarding proposed courses of action.

Saint-Pierre et Miquelon: Marie-France Télétchéa

Eastern Health provides services to patients from Saint-Pierre et Miquelon under a contractual arrangement with the French government. This includes treatment for breast cancer patients.

Mme. Marie-France Télétchéa is a resident of Saint Pierre et Miquelon. Her first language is French and she testified before the Commission with the assistance of an interpreter. She was diagnosed with infiltrating ductal carcinoma in St. John’s on October 30, 2000. An addendum to her pathology report was entered on November 8, 2000, stating “the immunoperoxidase stain for ER/PR shows no positive stain.”⁵⁰

She underwent a partial mastectomy of her left breast and subsequently a course of chemotherapy and radiation at the Cancer Centre. Upon completion of her treatment, she was usually seen for follow up by Dr. Gerard Farrell, a general practitioner who works in the

⁵⁰ Exhibit C-0200, p. 3.

Cancer Centre. During her visits at the Cancer Centre, she did not request the assistance of an interpreter and none was offered. If one of her treating physicians spoke in complicated medical terms, she would ask to have the language simplified. She felt she understood for the most part what she was being told, but she was very preoccupied at the time with the fact that she had been diagnosed with breast cancer and was to have chemotherapy. She does not recall whether her physicians discussed her hormone receptor status and its significance with her at the time, but she thinks they probably did.

During her follow up over the next five years, she would have mammograms in Saint-Pierre and bring the reports, written in French, to her treating physicians at the Cancer Centre in St. John's. Dr. Farrell notes on January 24, 2005, in reviewing reports brought to him by Mme. Télétchéa, that there was no translator available to translate the reports and so he sought the assistance of Dr. Joy McCarthy, who had some knowledge of French.

In June 2005, Mme. Télétchéa was unable to come to an appointment because Dr. Pascale Malluret, the *Medecin-Conseil*, Service Medical for Saint-Pierre et Miquelon, who could authorize treatment outside Saint-Pierre, felt that she could be followed up at home. She was next seen by Dr. Farrell on September 21, 2005. He wrote in the Progress Note for that date, "This lady was supposed to come back in June but I gather that the appointment was cancelled. There seems to be some disruption in the follow up of our cancer patients from St. Pierre." At this visit, Mme. Télétchéa was not advised of any re-testing of ER/PR tests and was scheduled to come back in six months. She feels she should have been informed of the re-testing before her sample was re-tested.

Mme. Télétchéa first heard of the re-tests after receiving a phone call from her gynaecologist, Dr. Michel Peudecerf. He had received a letter from Eastern Health stating that Mme. Télétchéa's results had changed and she should begin taking tamoxifen. Dr. Peudecerf, however, questioned the advice to take tamoxifen five years post-diagnosis and also cautioned Mme. Télétchéa that tamoxifen could cause uterine cancer. Armed with this information, she decided to do some

research of her own on the internet and it was there that she found a webpage about the problems that had been discovered with the tests at Eastern Health.

Mme. Télétchéa's tissue sample had been re-tested at Mount Sinai on October 5, 2005. On re-testing, she was ER and PR positive. Her case was considered by the Panel on October 27, 2005. A letter, in English, from Dr. Kara Laing on behalf of the Panel, dated October 27, 2005, was sent to Dr. Farrell and copied to Dr. Alan Kwan and Dr. Malluret. It stated that she should be offered treatment with tamoxifen, if that were not contraindicated. It is the panel letter that Dr. Peaudecerf received and read to Mme. Télétchéa.

Meanwhile, within Eastern Health, Ms. Heather Predham had been making efforts to arrange contact with the patients in Saint-Pierre. She had spoken with Dr. Malluret but was concerned that her fluency in French was "far from sufficient to explain the intricacies of this issue" so on October 25, 2005, she emailed Ms. Sharon Dominic, the Nurse Coordinator for Bilingual Services within Eastern Health, seeking her assistance with this communication. Early in the process, Ms. Predham had raised concern as to how to communicate with the patients from Saint-Pierre.⁵¹

Dr. Peaudecerf wrote Dr. Laing on behalf of Mme. Télétchéa, acknowledging the panel letter and asking why there had been a delay in the initial treatment. Dr. Peaudecerf asked, in essence, to be convinced of the benefit of tamoxifen to his patient this long after the diagnosis. In a letter addressed to Mme. Télétchéa dated November 24, 2005, Dr. Farrell responded to Dr. Peaudecerf's correspondence sent to Dr. Laing. While this letter was in English, Dr. Farrell forwarded a copy of it to Eastern Health's Bilingual Services on November 30, 2005. Mme. Télétchéa was advised by Dr. Peaudecerf that he had received a response to his letter. Dr. Farrell wrote, "There has been a recent review of ladies with breast

⁵¹ Exhibit P-2949; In an email communication from Ms. Predham to Deborah Thomas, July 18, 2005, in providing a draft of a patient letter she poses the question, "What about Saint-Pierre?" In preparing a flow chart of communications on October 7, 2005, she lists the residents of Saint-Pierre as an outstanding issue.

cancer in St. John's. As a result of this review, it was [here] determined that you would be a candidate for a drug called tamoxifen.... I can understand that a letter of this nature is very brief and probably leaves you with many questions. For this reason, I will be offering you an appointment here at the Cancer Clinic so that we can discuss this matter." Mme. Télétchéa was to attend at the Cancer Centre for an appointment for December 14, 2005, but Dr. Malluret would not approve the expenditure. Mme. Télétchéa understood that Dr. Malluret was of the opinion that since it was a St. John's laboratory that had made the mistake, it should be Eastern Health's responsibility, not Saint-Pierre's, to incur the cost of the visit to discuss the re-testing results.

Mme. Télétchéa faxed a letter to Dr. Farrell outlining her questions. She included in her letter reference to Saint-Pierre's position that the planned visit for December 14, 2005, was not their "problem" and therefore Dr. Malluret did not want her to come to St. John's. Following receipt of her letter, Dr. Farrell spoke with Mme. Télétchéa via telephone and he followed up this conversation with a letter to Dr. Peaudecerf on December 6, 2005. In that letter, he confirms his understanding that there is a problem with Mme. Télétchéa coming to St. John's and outlines the change in her treatment regime which he had discussed with her via telephone. Normally, he writes, he would have preferred to have met with her in person. There is no indication that Eastern Health made any overtures to Mme. Télétchéa to assist her in coming to St. John's to meet in person to discuss the ramifications of the change in her result. Mme. Télétchéa took it upon herself, however, to meet with Dr. Farrell during a later scheduled trip to St. John's.

On February 8, 2006, Ms. Predham wrote to Ms. Dominic advising her that eight patients from Saint-Pierre had been re-tested. Ms. Predham had already been in contact with Dr. Malluret in October 2005, and she asked that Ms. Dominic convey the information regarding these patients to Dr. Malluret to ensure accurate communication. Of the eight who had been re-tested, two patients had their results change on re-test, one of whom was Mme. Télétchéa. Ms. Predham attached to her correspondence the panel letters pertaining to those two patients. Four patients had no change in their results. Ms. Dominic was asked to contact

these patients to inform them that they had been re-tested and that their results remained the same. The remaining two patients were deceased and Ms. Predham indicated in her letter that a decision had been made to defer notification of these families until all other patients had been reviewed. There was a ninth patient whose results were not yet back. When this information was available, Ms. Predham explained, it would be conveyed to Ms. Dominic for her to provide to Dr. Malluret. Ms. Dominic forwarded this letter, without translating it, to Dr. Malluret on February 15, 2006. She included a handwritten cover note in French which asked Dr. Malluret to contact the two patients whose results had changed. The panel letters for these two individuals were attached. Of course, Dr. Malluret had already forwarded Mme. Télétchéa's letter to Dr. Peudecerf some months before.

A review of the NLCHI database for information on the contact of the Saint-Pierre patients is not of much assistance in determining if, in fact, contact was made with those patients. For example, with respect to the "confirmed negative" it notes "notified of results via St. Pierre." There is no date given for these contacts, nor is the identity of the person making the contact or the source of this information provided. As discussed below, this could be problematic. For Mme. Télétchéa, on the one hand, the database says the results were communicated by Eastern Health to a physician with no panel letter and elsewhere in the database there is reference to a panel letter. Clearly there was a panel letter in her case.

In 2008, Dr. Michel Bondonneau, who had replaced Dr. Malluret, became involved in this matter. On March 27, 2008, he wrote to Eastern Health's Board Chair, Ms. Dawe, seeking an official list of patients from his region. Not having received a response to this correspondence, he wrote to Dr. Howell on May 7, 2008, and asked for assistance in answering questions for patients. Dr. Bondonneau had taken the initiative of speaking publicly on this issue and had asked patients to come forward and identify themselves. He then compiled a list of patients and forwarded it to Eastern Health. Ms. Predham reviewed this list and provided Ms. Dominic a response for each patient identified by Dr. Bondonneau. She also identified four additional patients who were

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not on Dr. Bondonneau's list. In May 2008, other than for Mme. Télétchéa and the other patient who had had a change in results and for whom a panel letter was written, there was no indication of contact with the patients regarding the outcome of the re-tests.

In correspondence dated July 2, 2008, Dr. Howell told Dr. Bondonneau that he had met with Ms. Andrée Olano, the president of a not-for-profit group, ARVEL, which was formed to represent the patients affected by the ER/PR testing. Ms. Olano had asked that all patients who had been re-tested receive their original and re-test results. Dr. Howell informed Dr. Bondonneau that he told Ms. Olano that Eastern Health had sent the results to the chief medical person for Saint-Pierre et Miquelon for communication to the patients. It is to be noted, however, that the handwritten cover note from Ms. Dominic to Dr. Malluret had only asked that she contact the two patients who had changed results. Furthermore the attached letter to Dr. Malluret stated that Ms. Dominic was to notify the confirmed negative patients and that there had been a decision to defer notification on the results of the deceased patients. Given the ambiguity surrounding the contact of the patients from Saint-Pierre et Miquelon, it is advisable that further investigation be undertaken to ensure that all patients have been contacted.

In February 2008, Eastern Health publicly announced that all samples of deceased patients had been re-tested and that the families of those patients could obtain the results by making contact with Eastern Health. This notice was not published in Saint-Pierre et Miquelon. Two of the patients were deceased at the time of the re-test of their samples. One of those patient's results changed; the others did not. Eastern Health has provided email communications confirming that in August and September 2008, Ms. Dominic telephoned representatives of both of those families and conveyed the results of the re-tests. Such Eastern Health initiated direct contact with the families of deceased patients has only occurred for the patients of Saint-Pierre et Miquelon. Further, unlike Ms. Nancy Parsons, who was also a nurse, Ms. Dominic was authorized to disclose changed test results.

On June 30, 2008, Louise Jones as acting CEO of Eastern Health wrote an apology letter to Mme. Télétchéa. This letter was in French and it offered contact information for the Bilingual Office of Eastern Health. Mme. Télétchéa had heard through the media some months earlier that patients had received such a letter. This apparently had not included the Saint-Pierre patients. She felt the letter was rather late in coming.

Overall, Mme. Télétchéa was dealt with by Eastern Health in the same manner as other patients. The difficulties she encountered in communications pertaining to the re-test process were largely related to the language barrier and the additional bureaucratic hurdle that she faced in seeking medical services outside her own country.

ATIPPA Requests

The *Access to Information and Protection of Privacy Act* (ATIPPA), SNL 2002, c. A-1.1, is applicable to regional health authorities. In the course of dealing with the ER/PR problem, Eastern Health was consulted on Government's responses to ATIPPA requests and received ATIPPA requests itself.

On February 23, 2006, Mr. Reginald Coates, Access to Privacy Coordinator, Department of Health and Community Services, wrote to Mr. Tilley to provide him with a draft response to an ATIPPA request concerning ER/PR testing that the Department had received. Since much of the material relating to the request "resided" with Eastern Health, Mr. Coates sought Mr. Tilley's opinion on the draft response. Mr. Coates had identified certain emails as being exempt from production because they contained personal information. He saw no impediment to releasing the briefing notes relating to the subject. However, as a result of the consultation with Eastern Health, a paragraph from the July 20, 2005, briefing note for the Minister, which had provided the initial information regarding the problem, was deleted from the documents released in response to the ATIPPA request. That paragraph stated:

Eastern Health Vice president of Quality, Diagnostic and Medical Services Dr. Robert Williams has also asked that an investigation be conducted into the five-

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week stoppage of immunoperoxidase staining for ER/PR receptors in 2003 by Dr. Ejeckam.⁵²

Mr. Coates recalled that the paragraph was deleted at the request of Mr. Tilley, on the basis that the information contained in the paragraph was part of quality assurance measures and, therefore, the information was protected by s. 8.1 of the *Evidence Act* RSNL1990, c. E-16 which, in turn, under ATIPPA regulations, was exempt from the application of ATIPPA. Mr. Coates understood that as the paragraph would be exempt from the application of ATIPPA, he should not even refer to the deletion of the material in the response to the request. Mr. Coates explained that there were three categories of information that might not be provided under an ATIPPA request: where ATIPPA directs that the information not be provided, where under the exercise of discretion it is determined that the information should not be provided, and where ATIPPA has no application. In respect of the first two, if the information is not provided, the response will state that and under which section, or subsection, the information is not being provided. As to the third category, there is no reference in the communication to the existence of the information. In the material provided to Mr. Quinn, the paragraph was deleted and he was not told that there had been a deletion. Consequently he would have had no opportunity to pursue the question of whether the legislation was properly applied.

Mr. Tilley advised the Commission that he had asked that the paragraph be removed on the advice, he believed, of someone from the Quality Department. He confirmed that the reason articulated was that the paragraph related to quality assurance and therefore was protected information. He could not explain why that would apply to the paragraph related to Dr. Ejeckam's actions but not to the information that "a technology consultant from Mount Sinai will be reviewing our laboratory to assess the immunoperoxidase system. At that time, we will ask the consultant his or her opinion of the past several years' results under the DAKO methodology and for advice on the future direction of the immuno service." At the time, Ms. Predham was the ATIPPA

⁵² Exhibit P-0401.

coordinator at Eastern Health.⁵³ She says that she was not consulted on the issue by Mr. Tilley and did not provide any advice to him regarding the ATIPPA request to the Department. Further, she stated her opinion that the paragraph deleted did not meet the criteria for deletion. I accept Ms. Predham's testimony on this point.

By March 15, 2006, Eastern Health had received its own ATIPPA request from Mr. Quinn. Ms. Predham emailed Dr. Williams, Ms. Bonnell, Ms. Pamela Elliott, Ms. Pilgrim, Ms. Gulliver, Dr. Cook, Dr. Denic, Ms. Smith, and Mr. Tilley. She advised them that she would not be handling that request "since I've been so involved we certainly won't want any perception of bias in completing the request." The person who would do so was not yet identified. Ms. Predham, conscious of the time limits for response to such requests, asked them to gather all information they had, and reminded them that they would have to search their computers, including emails. She further noted that when the information was gathered they would have to determine what information would have to be excluded. On that point Ms. Predham said: "the two biggest issues will of course be the personal information and information pertaining to a quality review, and therefore protected under the Evidence Act." On March 16, 2006, Ms. Predham emailed those same individuals to tell them that the search for documents would cover the period from May 1, 2005, to March 10, 2006.

On March 27, 2006, Ms. Predham advised that Ms. Deanne Emberley, also of the Quality Department, would be coordinating the request. She also advised that Mr. Dan Boone, the solicitor for HIROC, had told her that there was an additional exception: "anything Dan was present for could be identified as being solicitor privileged." Ms. Predham asks that they advise Ms. Emberley as quickly as possible when she can expect to receive the information. Ms. Pilgrim replies within the hour, "I do not have a file on this. Obviously, I have been deleting the information as it has come in. So, there will be nothing forthcoming from me."⁵⁴ If there was a protocol regarding information management in

⁵³ As Ms. Predham described it, she had been an ATIPP coordinator for Healthcare and was acting in that capacity for Eastern Health on an interim basis.

⁵⁴ Exhibit P-3166.

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Eastern Health, there did not seem to be any impediment to an employee making a personal decision regarding what was to be preserved. One wonders if employees, like Ms. Pilgrim, would destroy letters in the same way as they deleted emails.

On April 26, 2006, Ms. Predham sent to Ms. Emberley a draft of the letter to Mr. Quinn responding to his ATIPPA request. That letter explains that where access was refused it was on one of three grounds: documents pertaining to quality review for which section 8.1(3) of the *Evidence Act* RSNL1990, c. E-16 was cited as the reason for refusal, documents containing personal information, and documents containing solicitor and client privilege. Unlike Mr. Coates, Eastern Health had advised Mr. Quinn that access was being denied to quality review documents. Ms. Predham stated that she had been on holiday during most of the time from the original request to the response. However, she returned to work the day before the response was sent to Mr. Quinn and because she had the templates for the response on her computer, she prepared the draft of the letter to go to Mr. Quinn.

In February 2007, Mr. Quinn was seeking additional information from Eastern Health. This time he wanted de-identified original test results and, under ATIPPA, re-test results for all patients whose ER/PR specimens were re-tested. Eastern Health declined to disclose the information on the basis that it was personal information. The letter came from Ms. Marian Crowley, who was then Access to Information Co-ordinator for Eastern Health. Mr. Quinn was advised that an affidavit outlining a summary of the results of the ER/PR testing had been filed in the Registry of the Supreme Court of Newfoundland and Labrador and that the document was available to the public. Mr. Quinn used the information from the affidavit as a basis for his May 15, 2007, story and the matter once again became the subject of public commentary. Mr. Quinn and others compared what they had understood from the information provided to the public in December 2006 and that contained in the affidavit.

In June 2007, Mr. Rob Antle of the *Telegram* filed ATIPPA requests with the government, seeking briefing notes relating to ER/PR testing.

Whether because the requests related to ER/PR, or because they related to briefing notes, Mr. Coates believed that the requests garnered more interest than usual from the Premier's office. That position was subsequently disputed by Ms. Renée Pendergast. Mr. Coates was instructed to produce copies of the documents relevant to the request for Mr. Brian Crawley, Ms. Elizabeth Matthews, and Mr. Brian Taylor. There followed some difference of opinion within Government regarding the interpretation of the legislation. This included such things as whether the questions in the Questions and Answer Briefing Notes were properly within an exemption or should be released.

Letters of Apology

In the spring of 2008, Ms. Pilgrim, Chief Operating Officer, asked for an ethics consultation. The purpose of the consultation was said to be to discuss appropriate actions to respond to concerns related to the ER/PR situation from patients and families. The facilitator for the consultation was Dr. Rick Singleton. In his report on the consultation, Dr. Singleton described the context of the consultation. The Commission's public hearings were said to have caused an increase in the number of calls being received by Eastern Health. In some cases, the patients claimed that they had not been contacted about ER/PR when their records revealed that they had been called. In some of those cases, the patients had not understood the conversations they had originally had with Eastern Health about ER/PR.

Dr. Singleton reported that the consensus of the group was that steps ought to be taken to clarify the situation for patients and their families. The report stated:

The EH Core Values of Respect and Integrity prompt us to take these steps. The principle of beneficence (to do good) and nonmaleficence (do no harm) add further support to take action to provide information to those impacted. The Principle of Justice leads to acts to correct wrong or misleading information that is causing distress, perhaps interfering with important therapeutic relationships, and complicating the health and wellbeing of the individuals.

It was recommended that letters be prepared for everyone in the four major categories of patients tested in the time period being reviewed by the COI: Patients tested with no change; patients tested with change in ER PR value and

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no change of treatment, patients tested with change in ER PR value and change of treatment, and patients retested who ought not have been retested.

The letters should be tailored to the individuals in each category to review the details of their category, and the previous contacts (and efforts to contact) regarding disclosure of their individual cases. The letters should also contact [contain] a number and e-mail for further contact.⁵⁵

In 2008, letters were sent to patients, who had been re-tested, but other recommendations of the ethics consult regarding categories of letters were not followed. As Ms. Pilgrim described it, in the end it was a decision by Ms. Louise Jones, the acting CEO of Eastern Health. The letter was described by Ms. Pilgrim as having evolved into an apology letter with form attachments. Ms. Pilgrim indicated that the attachments were included as a result of consultations between Eastern Health and the Canadian Cancer Society, and with a patient who had suggested information patients might like to receive.

Ms. Pilgrim advised that the response of patients varied, with some accepting the apology and others indicating it was too little too late.

⁵⁵ Exhibit P-2826.

Chapter Twelve

Communications Part III: Recurrent Themes and Influences

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Recurrent Themes

The communications related to ER/PR had certain recurring themes, most of which were well established before the story became public on October 2, 2005. The most influential of those are examined below.

(1) *A system problem*

James Reason created the “Swiss Cheese Model of System Accidents.”¹ This model, which was referred to in the testimony of at least four senior executives from Eastern Health,² provides a way of explaining system failures. Reason believed that “accidents” could be traced to one or more of four types of failure: organizational influences, unsafe supervision, preconditions for unsafe acts, and the unsafe acts themselves. The Swiss Cheese Model uses a series of slices of Swiss cheese to represent barriers to patient harm. The holes in the cheese demonstrate weakness in the system. As Reason noted (2000, p. 768, as quoted by Dr. Sherry Espin), “The presence of holes in any one slice does not normally cause a bad outcome.” The holes,³ however, are not static; they open and close and vary in size. Patient harm occurs when the holes line up, thereby permitting a hazard to pass through all the holes in the defences. Reason argues that nearly all adverse events involve a combination of active failures and latent conditions.⁴

Mr. George Tilley explained that when Eastern Health said or suggested that ER/PR was a systems problem (sometimes called a “system failure”), the term was meant to refer to a

¹ It should be noted that Reason’s model has changed over time. It can generally be said that the 2000 version is a simpler one.

² Mr. George Tilley, Ms. Louise Jones, Dr. Robert Williams, Dr. Oscar Howell.

³ A hole may be an active or a latent error.

⁴ Volume 2 of this report.

situation that was beyond one particular person. He added (April 24, 2008):

But the use of a system problem is one that seems to be used fairly wide spread in the health care community, and it's meant to [apply] when there appears to be, you know, multiple factors that could, in fact, be leading to a particular outcome. So you mentioned technology, yes, technology could possibly be a part of that. The Ventana system I know has been talked about some as the system. Certainly the system wasn't intended to be referring just [to] the Ventana.⁵

However, an examination of Mr. Tilley's evidence shows that he used phrases like "Ventana system" in circumstances where it was clear he was referring to the instrument alone.

A statement that the Ventana Benchmark or the Ventana system was more sensitive obviously refers to the instrument itself and pre-diluted antibodies. However, Dr. Beverley Carter said in a memo to Dr. Robert Williams and Dr. Donald Cook, dated August 8, 2005: "From these very preliminary and very raw numbers I believe that the idea that the DAKO system - both its performances and interpretation - greatly underestimated the number of women who would benefit from hormonal manipulation of their breast cancer and should be investigated."⁶ She must have been referring here to the total process of testing, which includes the interpretation done by pathologists. What makes that abundantly clear is Dr. Carter's reference to interpretation.

In my view, anyone reading accounts of the interviews given by Eastern Health officials, the materials provided at their briefings, or their public statements would understand that when an Eastern Health official spoke of the Ventana system or the DAKO system, he or she was talking about the instruments. First, even if they intended to convey some message that the problem was caused by a combination of many things, as in the holes lining

⁵ Transcript of testimony, George Tilley, April 24, 2008, p. 40.

⁶ Exhibit P-0081.

up in the Swiss cheese analogy, it is unlikely that without elaboration the average reader or listener would appreciate the special meaning attributed to the term within the health care community. Second, there are so many places where the meaning is clearly a narrow one that the narrow one is the interpretation more likely to have been understood by the reader or listener.

I am satisfied that in the many references in Eastern Health's materials to the new more sensitive Ventana system; the Ventana Automated System; the reagents used in the Ventana system; the older DAKO system; a new system being installed; or in phrases such as "to confirm that it was indeed the system and not a lab error,"⁷ and "new crackerjack system,"⁸ the word "system" was not intended to refer to anything other than an instrument.

There were some exceptions to this. One is the reference by Dr. Carter, cited above, where her meaning is clear because of the words "which includes the interpretation done by pathologists." Two others come from Mr. Tilley, one in a presentation he gave to a CPSI Conference, in which he described the problem as a "systems issue not a typical medical error" and in a note taken about the August 1, 2005, meeting, where Mr. Tilley recorded:

System error

- Lab equip
- Pathologists - different pathologist
- Oncologists - turnover

The only communication outside Eastern Health in which the problem was described as a system failure was at the CPSI conference, and even there the meaning is equivocal. Time and again, witnesses stated that they understood that the problem related to the old DAKO system. Examples are Dr. Larry Alteen in March 2006 and Ms. Deana Stokes-Sullivan in December 2006. The

⁷ Exhibit P-0075.

⁸ Transcript of testimony, Darrell Hynes, June 18, 2008, p. 273.

first was a physician who would have had more than the average person's knowledge of the ER/PR problem. Ms. Stokes-Sullivan was a reporter experienced in health matters, though this issue was new to her. It should also be noted that Ms. Joan Dawe, the chair of the Board of Trustees of Eastern Health, and not a stranger to the issue, believed, as a result of the briefing of the Board of Trustees in September 2005 that the problem could be traced to technology. When asked how long that belief continued, Ms. Dawe replied:

I can't give you a month or a specific time when – because I think any briefing notes that or press releases always referred to a change in technology and a change of systems. So I had no reason to eliminate that as a possible and I'm not even sure today, is it completely ruled out as a factor.⁹

(2) *More sensitive Ventana Benchmark*

I have already commented on the notion within Eastern Health that the Ventana Benchmark was more sensitive and that its sensitivity might be an explanation for the changes in results being observed by Dr. Carter during her 2005 review. The implication of such statements is that the Ventana Benchmark was capable of discerning ER positivity where the DAKO Autostainer could not. Another way Eastern Health expressed it was that the Ventana Benchmark is an improvement in technology.

Dr. Williams agreed that in the summer of 2005 there were some in the Group who were speculating that the difference in results could be attributed to the Ventana technology being better because it removed so many problematic steps from the procedure. Dr. Williams indicated, however, that he was not among those people, and that he knew that certain laboratories were getting good results on semi-automated systems. There is no indication that Dr. Williams did anything to disabuse others in the Group of the notion that improved technology explained the changed results.

⁹ Transcript of testimony, Joan Dawe, March 26, 2008, pp. 187-188.

In a story in the *Telegram* shortly after the matter became public in October 2005, Dr. Williams was cited as the source of the information that the reason for the discrepancy in the breast tissue results was not clear, but during the previous year Eastern Health had implemented a new, fully automated system for detecting hormone receptors in breast tissue. The reporter, Ms. Stokes-Sullivan, added:

Williams said the older system was semi-automated and the testing involved multiple steps, including boiling or microwaving specimens to “tease out the antigen from the nucleus of the cell so the staining would be taken up by the antigen if there are receptors there.”

It was the new automated system that yielded conflicting results on retesting.¹⁰

As early as the May 24, 2005, letter to Dr. Williams from Dr. Cook, Dr. Cook said it had been agreed with the oncologists that if there were a receptor conversion in the re-tests being done at the time, “the oncologist would inform the patients that we have retested the ER and PR receptors under our new more sensitive technique.”¹¹ Ms. Heather Predham in her testimony, Mr. Tilley in his notes of July 19, 2005, and Ms. Deborah Pennell in her notes of July 20, 2005, all commented on their understanding at the time, which was that the Ventana Benchmark was more sensitive or ten times more sensitive. There were references to the Ventana Benchmark being more sensitive in the draft briefing notes and media releases prepared by Strategic Communications in July 2005, when they were preparing for an anticipated public announcement. One draft media release was headed “Retesting due to improved technology.” A similar phrase was used in a letter drafted by Strategic Communications for possible communication with patients.

¹⁰ Exhibit P-1662.

¹¹ Exhibit P-0324.

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On July 22, 2005, however, Ms. Susan Bonnell gave Mr. Tilley her advice regarding the question of whether there should be a public announcement. In that context she says:

As it stands today, we do not know why we are achieving a high rate of conversions in those specimens that have been retested. Is this a case of increased sensitivity due to the new technology that exposes the limitations of the former manual process, or were the tests performed incorrectly? We cannot answer this question, so we risk confusing and upsetting patients and their families and unnecessarily calling into question the professionalism of the lab.

We cannot say that we have a new piece of technology that is more sensitive and therefore we are retesting old negatives because if we are retesting in this case, why wouldn't we do it every circumstance where new technology improves our ability to diagnose and treat illness? Furthermore, to state that this is about technology would be only partially truthful as the organization feels that there is a *possibility* of error that must be investigated. If asked the question, "How did this come to your attention?" then it would appear that our actions were obfuscatory rather than open and honest.¹²

Around the same time, Dr. Kara Laing was questioning whether the Ventana Benchmark might be over-sensitive. The meeting of August 1, 2005, has been referred to on a number of occasions. In that meeting, Dr. Carter made it clear that it was her opinion that the change in machines did not explain the problem. Ms. Predham also remembered very clearly having been told at that meeting by Mr. Terry Gulliver that it was not that the Ventana Benchmark was more sensitive but that it was more consistent. Ms. Bonnell said that she understood after August 1 that it was not the machinery that had caused the problem. For those in the Group, the notion that the ER/PR problem could be explained by the sensitivity of the Ventana should have been completely dispelled at the meeting of August 1, 2005.

Ms. Bonnell asserted that phrases such as "more sensitive" did not find their way into materials produced later by Strategic Communications because they learned that the changes in test

¹² Exhibit P-1488.

results were not due to improvement in technology. Further, the plan for re-testing was later changed and it was not being done on the Ventana Benchmarks in-house but at Mount Sinai.¹³ Ms. Bonnell maintained:

Over a period of time I certainly cautioned others about using it [improved technology]. And, you know, beyond, beyond October the concept of improved technology, we talked about the Ventana and we talked about the impact that the new technology had on more consistent results, that was talked about later on, but never that this was due to improved technology.¹⁴

She conceded, however, that an uninformed listener might have concluded, on the basis of the information about the implementation of the Ventana Benchmarks that the change in results was due to the technology change. Ms. Predham agreed with Commission counsel's suggestion that Eastern Health "went out and told the public that it was due to technology after it knew it wasn't."¹⁵

The suggestion that the Ventana Benchmark was more sensitive had influence beyond Eastern Health. When, on June 14, 2005, Dr. Cook wrote to the laboratory directors for the other regional health authorities regarding sending their blocks for 2002, he said: "This new Ventana system is fully automated and is much more sensitive than the immunoperoxidase technique under the previous DAKO method."¹⁶ After the ER/PR story appeared in the *Independent* on October 2, 2005, this phrasing was reflected in a briefing note prepared for the executive of Central Health.

When a briefing note was being prepared for the Minister of Health and Community Services, Mr. John Ottenheimer, immediately before the meeting of July 21, 2005, there were two references to the sensitivity of the new equipment. In one case,

¹³ Of course, at Mount Sinai the re-testing was being done using a DAKO Autostainer.

¹⁴ Transcript of testimony, Susan Bonnell, May 29, 2008, p. 136.

¹⁵ Transcript of testimony, Heather Predham, October 17, 2008, p. 134.

¹⁶ Exhibit P-0492.

that sensitivity was linked to an expectation that there would be greater accuracy on testing. Mr. Darrell Hynes recalled that in the meeting with Mr. Ottenheimer of July 21, 2005, it was said that the explanation for the changed results could be “the new technology was more sensitive and it was picking up ...that the technology was much better and this is why we were picking up all these new cases.” Neither in the briefing note nor in the meeting was the Minister cautioned that another explanation might be that the tests were not performed correctly. Yet, the next day, Ms. Bonnell, in a memo to Mr. Tilley, stated that there was “a *possibility* of error [in performing the tests] that must be investigated.”¹⁷

Mr. Tom Osborne, who replaced Mr. Ottenheimer as Minister of Health and Community Services, also recalled receiving information that the Ventana Benchmark was a more sensitive machine. This idea was still being reflected in briefing notes of the Department of Health and Community Services in December 2006, and a press release from Eastern Health on May 18, 2007, still referred to re-testing on the “new, more sensitive Ventana system.”¹⁸ Long after the members of the Group knew that the problem could not be attributed to the sensitivity of the Ventana Benchmarks, the notion of improved technology or a more sensitive Ventana Benchmark being the reason for the changed results continued to resonate. Eastern Health did nothing to disabuse others of the notion.

- (3) *Eastern Health’s decision to re-test large numbers of cases was unprecedented*

In its submission to this Commission, Eastern Health said at para. 629:

The decision to retest all negative specimens was the single most important response to the discovery of potential unreliability of the original tests. That response was an unprecedented one. It was taken in

¹⁷ Exhibit P-1488.

¹⁸ Exhibits P-0125 and P-0443.

the interest of the patients. Those involved recognized that there would certainly be negative consequences, and possibly quite serious ones, for the organization and for the people in it.¹⁹

I have already stated my view that Eastern Health had no choice but to re-test, given their knowledge of the situation in the summer of 2005. The small group of people who met on May 17, 2005,²⁰ made a decision to investigate further. That was an appropriate professional response to the situation. One would expect no less from them. The same must be said of the decision to proceed with Dr. Carter's plan to investigate the problem and, ultimately, the decision to re-test all patients at Mount Sinai.

The decision to re-test all of the negatives certainly was out of the ordinary. Luckily, there are few adverse events of this magnitude. Was it unique? Had this been a situation where there was a new and better instrument which allowed one to do what an earlier instrument did not, as Ms. Bonnell pointed out, it would not be expected that one would re-test everyone who had been tested on the older machine. A decision to re-test hundreds of patients in that circumstance would have been unique. But that is not what this was.

There have been situations in the past where extraordinary efforts have had to be made to re-test patients. In *Gynaecological cytopathology and the search for perfection: Civil liability and regulatory ramifications*,²¹ the author, Mr. Ian Freckelton, discusses a number of false negative "scandals" where there was re-testing or re-examination of thousands of pap smears. In the submission of the Healthcare Insurance Reciprocal of Canada (HIROC) in respect of Part II of the Inquiry, Professor Elaine Gibson's Memorandum includes reference to the case of *Pittman Estate v. Bain*²² which arose out of the tainted blood scandal. In that case the Canadian Red Cross Services and the Toronto General Hospital had a duty

¹⁹ Submission of Eastern Health, para. 629.

²⁰ Dr. Laing, Dr. McCarthy, Dr. Carter, Dr. Cook, and Mr. Dyer.

²¹ (2003) 11 JLM 185.

²² (1994), 112 D.L.R (4th) 257 (Ont. Gen. Div.).

to look back to ascertain which patients had received potentially harmful blood, indicating what great efforts must be undertaken in such cases to uncover the identity of patients who might be harmed. There is no doubt that, in deciding to re-test, Eastern Health made the correct decision, but it was not without precedent.

(4) *Eastern Health contacted every patient*

This theme did not emerge until 2006. After the ER/PR story broke on October 2, 2005, there was a very busy period during which patients were being notified of the re-testing, results were being sent from Mount Sinai to Eastern Health, and more blocks were being sent to Mount Sinai by Eastern Health. During that time, Eastern Health's messages to those outside its organization clearly stated that all patients who were being re-tested were being contacted. By November, Ms. Moira Hennessey was looking for information on the status of the contacts with patients about re-testing. She said in a message to Mr. Tilley: "We need to ensure that the Minister can state all patients have been contacted when the House opens later this month."²³ That was not possible in the fall of 2005, nor could such an assurance have been offered by Eastern Health in the fall of 2005.

It was 2006 before there was a public statement by Eastern Health that all patients had been contacted. In his August 4, 2006, written statement to the *Current*, Mr. Tilley said: "our clinical team members have communicated individually with all patients impacted by this review." Earlier in that statement he said that most patients had been notified of test results. The reference to contact with impacted patients must have related to the calls to advise patients that they were to be re-tested. The quoted passage later appeared in a Department of Health and Community Services briefing note. However, on October 20, 2006, Mr. Hynes' notes from a Department of Health and Community Services

²³ Exhibit P-0096.

Executive meeting included: “ER/PR – after a year – all patients still not notified.” Mr. Hynes testified that he recalled that referred to patients not having been contacted at all.

By 2007 there are frequent references to all patients having been notified. During the May 18, 2007, press conference, Mr. Tilley said “It is important to stress here and for you to know that we contacted each and every patient who was affected by this test review, making sure that they receive all of the information and support that they required.”²⁴ In May 2007, Ms. Elizabeth Matthews cautioned that accuracy in the backgrounder to the government’s announcement of the establishment of the Commission of Inquiry on Hormone Receptor Testing is important. She noted that in some cases the contact with the patients was through their physician. The backgrounder released by the government at time of the Press Release regarding the appointment of a Commission of Inquiry stated: “Eastern Health contacted each patient who was affected by the ER/PR test review or their family physician to make sure that they received all the information and support they required.”

In an advertisement placed in newspapers in June 2007, Eastern Health claimed:

We called all patients whose samples were being re-tested... We informed all patients and their doctors of their individual test results.²⁵

Ms. Predham denied that she had told Mr. Tilley that everyone had been contacted. “I’ve never said that in my life.”²⁶ Indeed, a number of witnesses confirmed that Ms. Predham had repeatedly said that there might be patients they had missed. However, in an email to Mr. Tilley on May 16, 2007, Ms. Predham wrote: “I guess the key point of clarification is that all the patients who need to know, knows ... it’s the general public and the media that doesn’t

²⁴ Exhibit P-0110.

²⁵ Exhibit P-0608, p. 3.

²⁶ Transcript of testimony, Heather Predham, October 22, 2008, p. 74.

have all the details and that is because it's before the court."²⁷ Ms. Predham testified that this email to Mr. Tilley was a quick response by her, which in hindsight she should have taken time to phrase more carefully. She said that she does not believe the CEO or VP of Medical Services at that point "would take a comment in an e-mail such as that as a fact and move forward with it."²⁸

Underlying Influences on Communications

(1) *The influence of the numbers*

The efforts by Mr. Gulliver to determine historic positivity rates for ER/PR testing done at the General Hospital were important to decisions regarding communications. They had no influence on the decision to proceed with the retrospective.

On July 20, 2005, Mr. Gulliver produced a document entitled: *REVIEW OF ER/PR STATS FROM 2000-2004/5*.²⁹ Within Eastern Health, the Group became so enamoured of the idea that positivity rates could demonstrate that their results were within an acceptable margin of error that the judgment of those in the Group was clouded for a period of time while they focused almost exclusively on those numbers. Acceptable or legitimate error rates in testing may be a relevant factor in a re-examining of laboratory testing. If one is dealing with a test that has an accepted margin of error, then the patient should not be led to believe it is infallible. It is a double-edged sword however. On the one hand, a change in results does not mean standards were not met. On the other hand, particular care must be taken when such tests are being done to ensure that proper quality assurance and quality control programs are in place in the laboratory performing such tests.

The figures gathered by Mr. Gulliver for the purpose of determining positivity rates should have been of interest for another reason. The period of time covered in his July 20, 2005,

²⁷ Exhibit P-0106.

²⁸ Transcript of testimony, Heather Predham, October 22, 2008, p. 222.

²⁹ P-0514.

report was shorter than that which was used for the re-testing. However, the document provided information that could have been used by Eastern Health to better assess the magnitude of the re-testing effort. For example, Mr. Gulliver's figures revealed that approximately 45% of all ER/PR tests originated from hospitals outside of St. John's. In subsequent calculations of the number of re-tests to be done, therefore, all figures based on St. John's results should have been approximately doubled to reflect this fact. On July 20, Mr. Gulliver had available to him the original test results for only those tests done within St. John's. His figures show the number of positives, number of weak positives, and number of negatives. Mr. Gulliver testified that for him a negative meant zero staining for ER and zero for PR, and a weak positive was a test result that was positive but was not clinically positive, as defined within Eastern Health during those years, or ER zero and PR positive. In other words, what Mr. Gulliver called a weak positive was considered a negative for the purpose of the re-testing subsequently done at Mount Sinai. On that basis, it is an easy exercise to determine the number of "negative ERs," as that was defined for the purpose of the re-test, for the period 2000 to 2004/5. That number, as of July 20, 2005, in Mr. Gulliver's report is 364. Interestingly, the report showed that the number of negatives dropped dramatically in the year 2003 and even more so in 2004/5. By July 27, 2005, Mr. Gulliver had added the data for 1999, which increased the number of negative ER re-tests to 424, with 1997 and 1998 yet to be added. These were not numbers that Mr. Gulliver kept private. Members of the Group saw them.

So then, when the Minister was being told on August 15, 2005, that the number of tests to be done was approximately 400, that was an underestimation of the number from St. John's, but more seriously and, to put it in the kindest way possible, no one thought to explain to the Minister that there were almost as many patients from outside St. John's to be re-tested. An estimate of 800 patients for re-testing provincially would have been considerably lower than the number ultimately turned out to be, but at least it would have had an air of reality, given the data available at that

time. To state the obvious, in the evaluation of time required to complete the re-tests, the number of re-tests to be done was an important factor. Eastern Health's estimate, determined early in the exercise, was never adjusted upwards until the re-testing was well underway and the blocks had largely been gathered and sent to Mount Sinai.

(2) *HIROC's influence and the Labrador class action*

Before turning to the influence of HIROC on the communications related to ER/PR, I digress briefly to comment on HIROC's role at the Inquiry. The Inquiry was divided into two phases, the first dealing with what happened to cause or contribute to the problems, when they came to light and whether they could have been detected earlier. It also dealt with what actions were taken by the responsible authorities when the problems became known. The second phase was directed to quality assurance and the duties of responsible authorities to patients. Part II emphasized the duty of disclosure within health care. HIROC applied to participate in both Parts. I granted standing for Part II but denied standing for Part I. My reasons for that decision can be found in Volume 3 and also on the Commission's website. For the purpose of this discussion I merely wish to point out that when HIROC made application for standing in Part I, it was on the basis that it was the insurer for Eastern Health. HIROC's applications stated, in part:

The issues which will be under consideration during Part I of the Inquiry and in respect of which the Commission is required by its terms of reference to make findings, are issues which will also be material to determination of civil actions for damages arising out of alleged fault in the operation of the ER/PR testing system during the relevant period. Consequently, it is the submission of *HIROC* that its interests could be affected by findings of the Commission within its terms of reference.

At no point in its September 2007 application for standing did HIROC suggest that it had any role in decisions made regarding the activities of a regional health authority. In being

granted standing for Part II, HIROC was entitled to ask questions of any witness with respect to issues related to Part II.

HIROC is an insurance reciprocal exchange that operates on a subscription and not-for-profit basis. It represents over 500 health care facilities across Canada, including Eastern Health. As one might anticipate, there are frequent contacts between Eastern Health and the solicitors for HIROC - so much so, that at times, it seems as if those who work for Eastern Health do not distinguish between their own solicitors and those who represent HIROC. In St. John's, HIROC is represented by the law firm Stewart McKelvey. Primarily, in respect of ER/PR, Eastern Health consulted Mr. Daniel Boone, of Stewart McKelvey. There is ongoing litigation related to the ER/PR matter and, consequently, Mr. Boone was not free to discuss many of his interactions with representatives of Eastern Health. However, where he was able to recount events, I found him to have a good recall. His statements about events witnessed by him were precise and unembellished.

Whether it intended to or not, HIROC influenced communications decisions by Eastern Health. It was most influential on the question of whether to communicate with patients about the fact that there was to be a re-test. This issue became linked in the minds of those involved to the Labrador class action.

Mr. Boone recalled that he first heard about the ER/PR problem at Eastern Health on July 16, 2005. Within the next few days he received, from Ms. Predham, materials regarding the issue and, from Mr. Michael Boyce and Ms. Eleanor Morton of HIROC, a voice mail indicating that Eastern Health might require legal advice related to the issue. It will be recalled that it was Ms. Morton and Mr. Boyce who, in a July 18, 2005, telephone conversation, discussed with Ms. Predham the Labrador class action case, as an illustration of a regional health authority adding to its problems by the method or timing of communication.

Mr. Boone attended a meeting on July 19, 2005, during which he was effectively given a briefing about ER/PR testing. It was during that meeting that Mr. Gulliver raised the matter of the positivity rates, suggesting that perhaps the problem might not be as large as they had feared. It was agreed that no further action would be taken until Mr. Gulliver completed his work on the positivity rates. At that meeting Mr. Boone also spoke to those in attendance about the possibility of an action for negligent notification either because of the choice to notify or the method chosen to notify. At the end of the meeting, Dr. Williams asked Mr. Boone if he was comfortable with the decision made that day to wait for Mr. Gulliver's additional figures. Mr. Boone replied that he was. At the Inquiry, he conceded that "That was an input, if you like into the decision." The decision had been to delay only a couple of days until the full numbers were produced. Dr. Williams' inquiry illustrates the value placed by Eastern Health on Mr. Boone's advice.

I cannot conclude that the information provided by Mr. Boone in the meeting of July 19, 2005, caused Eastern Health to abandon any plan to advise patients that the re-testing was going to take place. It was not as simple as that. I am satisfied, however, that as a result of Mr. Boone's comments on July 19, and during other conversations over the summer, Eastern Health correctly understood that HIROC was advising against sending such a letter. This is illustrated in an email dated October 24, 2005, in which Ms. Predham provided a summary of events to that point. She added:

Throughout all this time HIROC has been fully briefed and aware of our activity. Through Dan Boone they have provided feedback on correspondence to surgeons and family physicians and our media briefings. The only thing they have felt strongly about was sending a letter in July/August to all people whose samples would be retested. As there was no information about their individual results, we [are] still investigating to determine if there was a problem, and we were unsure of when the new results would be available. HIROC felt it would expose us unnecessarily to additional liability. This, of course, is from

their experience in Labrador, where the crux of the class action lawsuit was the notification and the unnecessary stress related to it.³⁰

It will be recalled that on October 18, 2005, after the issue had become public, Mr. Boone still opposed sending a letter to each patient, telling them that they would be re-tested. That same day, Dr. Williams instructed that notification of testing be done by telephone rather than by letter.

Dr. Alteen's notes of an October 6, 2005, telephone conversation with Dr. Williams reveal that by that date, 210 re-tests had been reported by Mount Sinai and 41 of those were conversions. The notes refer to the letters to be sent out by Dr. Williams to general practitioners and by Dr. Paul Gardiner to surgeons. Dr. Alteen also recorded:

HIROC - didn't want to disclose to patients until we have test results back. This cause [caused] unnecessary worry in Labrador last year when pts. contacted before results back...

- will try to arrange teleconference with CEOs/ HIROC to discuss³¹.

Dr. Alteen seemed to think the Labrador class action case had raised concerns about telling people without having the results of the repeat test back, because that might cause some people to worry unnecessarily. In fact, the circumstances of the Labrador case required the regional health authority to contact patients and advise them to be re-tested. In the decision on the application for certification of a class proceeding, Justice Russell stated that the Health Authority sent a registered letter to the patients "advising that due to its failure to properly sterilize the instruments ... patients were at minimal risk of contracting an infection." The Labrador patients were also advised of the need for testing to determine whether they had contracted certain diseases as a result of having been examined with improperly sterilized equipment. Comments in various communications indicate that few people understood what the Labrador class action was about. The

³⁰ Exhibit P-0309.

³¹ Exhibit P-2907.

misunderstanding about the Labrador Class Action seemed to add weight to Mr. Boone's view that there should be no letter advising patients that there was to be a re-testing.

Ms. Predham was able to cite a case where Eastern Health had not followed the advice of HIROC's solicitors.³² It did not happen often. Others, such as Mr. Tilley, had expressed concern about going public, but that was based on lack of information. Mr. Boone's stated argument was based on the potential for negligent notification. It is interesting that no one seemed to think Mr. Boone's concerns could apply to notification by telephone.

Analysis of the Communications Issues

In many ways Eastern Health found the communications relating to the ER/PR problem more difficult than the problem itself. Communications had its own special considerations. However, certain factors that caused difficulty with the re-testing also had an impact on communications. The most obvious of these is the lack of information management. The same difficulties Eastern Health encountered in trying to determine who should be tested influenced the ability to contact these individuals. The information management problems were not limited to the way data had been handled in the past. When the Group was formed, no one thought to include persons with skills in information management. For example, when the Newfoundland and Labrador Centre for Health Information (NLCHI) was in 2007 assigned the task of determining whether all patients had been contacted, the task was made more difficult by issues with data collection and management.

In their testimony, Ms. Predham and Ms. Bonnell made the point that I should not make too much of drafts of briefing notes or media releases or letters. They were, after all, only drafts, and could be easily revised as the circumstances demanded. In other words, Eastern Health was not wedded to a particular statement in those drafts and it would be improper to suggest that they represented fixed ideas. While I accept that draft documents are, by their nature, open to change, I do find the drafts

³² The circumstances of the case were not comparable to the ER/PR situation.

to be instructive. They record notions that, at the time they were written, had sufficient acceptance to be the basis of a draft position. No one would waste time on ideas that had been completely rejected by all. Equally important, certain ideas or theories or explanations of the ER/PR problem, having made it into a draft document, kept reappearing long after they should have been abandoned, based on the information available. In addition, Eastern Health was the source of information for other regional health authorities and the Department of Health and Community Services. Consequently, a statement contained in an earlier briefing note sometimes survived in another organization when it had been abandoned within Eastern Health.

The efficiency of the process was impaired by other factors. Ms. Predham made a telling point about the decision-making. The Group would discuss how best to contact the patients, for example, but instead of analyzing the pros and cons of each option and then making a decision with that information, they made decisions on broad policy bases and then, when attempting to carry out a decision, they would discover the practical problems associated with it. The only occasions when there seemed to be an analysis of the pros and cons of a proposed action was in Ms. Bonnell's work for Mr. Tilley, in which she analyzed the various communications options.

I have no doubt that when the public became aware of the scale of the ER/PR problem, as would inevitably happen, it raised doubts about testing within Eastern Health's laboratories generally. That is a natural reaction to a failure by an institution that has generally had the confidence of the public. However, in my opinion, the problem in this case was compounded by Eastern Health's communications choices. These included: the failure of the CEO to take the lead, the failure to acknowledge early on that there were errors and how big the problem was, and the failure to use others who could assist in conveying information and providing feedback, such as the Canadian Cancer Society. As Ms. Bonnell, in one of her memos, had predicted, by failing to comment publicly, Eastern Health encouraged the view that it was hiding information. Further, a siege mentality began to creep into corporate decision-making. Eastern Health was concerned that the

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Department of Health and Community Services had released briefing notes under ATIPPA requests. Ms. Predham was, therefore, expressing concern about putting certain information in writing when it was destined for the Department.

In most cases, it would be advantageous for regional health authorities to advise the public of large-scale adverse events, through the media and other channels. This would be done in the interest of maintaining, or restoring, public trust and confidence in the institution. A further side benefit of public knowledge of adverse events is that other health care bodies may review their systems to ensure a similar problem does not take place within their institutions. That is, it would promote patient safety outside the institution in which the adverse event occurred. In failing to communicate effectively and openly, Eastern Health undermined its own credibility with the public.

Chapter Thirteen

Peer Review

Peer Review

Peer Review and Quality Assurance Reports

Underlying Eastern Health's decisions regarding what was to be communicated to others, was the notion of confidentiality of peer review and quality assurance reports. The reports of Dr. Diponkar Banerjee and Ms. Trish Wegrynowski were seen as falling into one or both of these categories. The general perception was that one could not speak about what was contained within the reports except to a very select few. When the written reports were received in 2005, Eastern Health initially made only four copies. They went to Dr. Donald Cook, Mr. Terry Gulliver, Dr. Robert Williams, and Ms. Heather Predham.¹ Later the number of copies was increased to eight. Dr. Nebojsa Denic, who had by then replaced Dr. Cook as the clinical chief of laboratory medicine, and Ms. Patricia Pilgrim received copies. What happened to the other two copies of each report is not clear, though we know that there were copies in Mr. George Tilley's office for the Minister, but these were not sent by Ms. Louise Jones when she became acting CEO. Mr. Tilley himself did not receive a copy of the reports, though at some point he went to Dr. Williams' office to read them. Dr. Cook to read Dr. Banerjee's report to the pathologists on October 17, 2005 but they were not given copies.

As has been discussed, the ER/PR matter first came to the attention of the public on October 2, 2005, through the story in the *Independent*. Ms. Susan Bonnell and Dr. Kara Laing provided the information to the reporter. The story included information regarding the installation of the Ventana Benchmark, though it was not described by name. It was said however to be a "more accurate" piece of machinery. Dr. Laing sat in on the exit interview with Ms. Wegrynowski but in her comments to the reporter did not refer to anything said in the interview, even obliquely; because "that was part of a peer review process, I did not discuss it at all during this interview." Dr. Williams made a similar statement. Both felt constrained in what they could say publicly (or privately) when the source of the information was a quality review or a peer review. Their failure to reveal anything about why the results were

¹ In one case it was said to have gone to Ms. Predham/Ms. Elliott. Ms. Predham reported to Ms. Elliott at that point.

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now different, coupled with the fact that Eastern Health was touting the benefits of the newer machinery, led others to conclude that this was a case of better technology enabling Eastern Health to produce more accurate results. Eastern Health knew, at least by August of 2005, that this was not true. It did nothing to correct the erroneous perception of the origin of the ER/PR problem. The most obvious source of information respecting the reasons for the changes in results were the interviews and reports of Dr. Banerjee and Ms. Wegrynowski. The understanding of the Group was that the content of those documents could not be spoken of outside the very narrow circle referred to above. Dr. Beverley Carter's observations were not inconsistent with those reports and Eastern Health did not consider them to be protected, but her work was not referred to in any explanation of the problem.

Patients were told on re-testing either that their results had changed or were unchanged. If, following the review by the Panel, there was a clinically significant change, their physicians discussed the impact of that with them. If patients asked what caused the change to occur, the most common response was "we don't know" or "it is being investigated." There is no evidence that the cause of the problem was discussed in any more than the vaguest of terms with officials of the Department of Health and Community Services or either of the Ministers. Only Mr. Tom Osborne seems to have pursued the question with any vigour. He did not get an answer. He too thought it was a technology issue. While it appears that Mr. Tilley was going to send a copy of each of the reports to the Minister in 2007, he had not done so before he left his position, and his successor did not send the reports. It was almost two years after the ER/PR problem arose that the other regional health authorities learned of observations contained in the reports relevant to their operations. Even then, Eastern Health was uncertain if it could disclose this information to other regional health authorities.

A question that relates to this Inquiry's mandate is whether there is a conflict between the duty to disclose adverse events (or occurrences) to a patient, and perhaps to others, and section 8.1 of the *Evidence Act*, RSNL 1990, c. E-16. If there is such a conflict, how should it be resolved?

The notion of peer privilege was developed in the common law, where it is sometimes referred to as the Wigmore privilege. However, in all provinces of Canada, the common law has been replaced by legislation.² Justice Dymond addressed the purpose of section 8.1:

The intent of the legislation was to allow hospitals, and other institutions, to be able to carry out Peer Review and Quality Assurance Reviews of these two Committees in an open and frank manner without these communications, or written reports being accessible in any proceedings in a Court of law, the premise being that such protection would foster open and frank dialogue between the doctors, medical staff, technicians and other health care providers so as to encourage reporting of facts and information which would improve patient safety and lead to a better care and treatment of patients.³

The obvious assumption is that without such protections, patient safety would suffer because those with information would be reluctant to provide it or would be less than frank in expressing their opinions. An obvious weakness of such a system is that it concentrates on patient safety within a particular organization. If a patient who is involved cannot know what lessons were learned, how can a health care provider in another part of the province or country hope to learn from the event?

When peer privilege was being developed in the common law and when legislation granting protection or privilege was being enacted across Canada, generally speaking the right of disclosure had not arisen or was in its infancy. Many authors cite *Stamos v. Davis* (1985), 21 D.L.R. (4th) 507 (Ont. H.C.) as the first step in the development of a duty of disclosure in Canada. However, it was not until the late 1990s that the concept became well established; there are aspects of the duty of disclosure that are still not resolved.⁴ The legislative measures similar to those in s. 8.1 of the *Evidence Act* were introduced in the late 1980s or early 1990s, without consideration of the notion, then just beginning to be

² Justice Dymond held that in respect of Newfoundland and Labrador the provision of the *Evidence Act* had replaced the common law.

³ *Eastern Regional Integrated Health Authority v. Commission of Inquiry on Hormone Receptor Testing*, 2008 NLTD 27; see Volume 3, Appendix 9.

⁴ Manitoba, Quebec and Ontario have enacted legislation imposing a duty on regional health authorities or institutions to disclose adverse events. The common law duty has been expressed, to date, as a duty imposed on a physician.

articulated, of the patient's right to disclosure of adverse events. It was not until 2004 that the Code of Ethics of the Canadian Medical Association imposed an ethical duty on physicians to disclose adverse events to their patients.⁵ Section 8.1 of the *Evidence Act* does not represent some balancing of policy interests. Rather, it reflects one perspective only.

Further, just because one can generally state that peer privilege exists in all provinces, it does not follow that the legislation is identical. One of the basic differences is whether the legislation creates a statutory privilege or a prohibition against disclosure. The first may be waived by the beneficiary; the second may not. Section 8.1 of the *Evidence Act* falls into the second category. It affords protection and imposes a prohibition, only in the context of a legal proceeding⁶ as defined in the *Act*. So then, in October 2005, the *Evidence Act* did not prohibit either Dr. Laing or Dr. Williams from sharing information gained from the reports of Dr. Banerjee or Ms. Wegrynowski, nor did it prevent the sharing of information with other regional health authorities or the Minister of Health and Community Services. The only limitation on Eastern Health's ability to speak about the information provided by those two reports at that time was self-imposed. Whether there are any limitations outside the confines of a legal proceeding as defined by the *Act* depends on the meaning of "in connection with a legal proceeding." The earliest one could reasonably argue that the prohibition arises is on commencement of a legal proceeding. One could equally argue that if, in fact, the *Act* is designed to prohibit the use of the information only in the limited context of legal proceedings, then there is nothing to prohibit its use in any other forum. These questions have not been litigated in this Province. In certain other provinces and territories,⁷ the prohibition is not limited to the context of legal proceedings but is more general, attaching to all

⁵ Professor Gerald Robertson points out in his paper, "The Legal Duty of Physicians To Disclose Medical Errors," in Volume 2 of this Report, that the ethical duty imposed by the Canadian Medical Association Code of Ethics appears to be narrower than the legal duty.

⁶ "Legal proceeding" includes an action, inquiry, arbitration, judicial inquiry or civil proceeding in which evidence may be given and also includes a proceeding before a board, commission or tribunal, (s. 8.1(1)(a) of the *Evidence Act*).

⁷ British Columbia, Ontario, Nunavut, and Northwest Territories.

documents of a certain nature, much as Dr. Laing and Dr. Williams seemed to think that the Newfoundland and Labrador legislation applied.

Another difference between the legislation is that under some Acts, facts may be revealed to a patient, either because there is a specific exemption for facts or because the wording of the legislation is interpreted to permit such an exemption. HIROC has submitted that *Doyle v. Green* (1996), 182 N.B.R. (2d) 341, (N.B.C.A.), is authority for the proposition that “it is commonly accepted that any facts disclosed within a quality review which are not otherwise recorded on the health record must be disclosed to patients.” While I might hope that to be the case under s. 8.1 of the Newfoundland and Labrador *Evidence Act*, the language of the section⁸ is so broad that there is a reasonable possibility that the interpretation would include facts within the prohibition. That might effectively shut down any disclosure after the triggering event for the application of the section.

What does Disclosure Require?

Generally statements of the law limit the duty of disclosure to facts. Dr. Thomas Gallagher points out in his paper, “Disclosing Unanticipated Outcomes To Patients: International Trends And Norms”⁹, that the National Quality Forum, a US organization that articulates consensus standards for high quality health care, has added disclosure of unanticipated outcomes to its list of safe practices. That practice emphasized the importance of informing patients of “the facts” regarding the outcome, including its preventability. Canadian Patient Safety Institute (CPSI) guidelines also discuss what should be disclosed. These include: the facts of the harm and/or event known at the time; an expression of sympathy or regret; a brief overview of the investigative process that will follow, including appropriate timelines and what the patient can expect to learn from the analysis; and the plan for further

⁸ “No report, statement, evaluation, recommendation, memorandum, document or information, of, or made by, for or to, a committee to which this section applies shall be disclosed in or in connection with a legal proceeding” (section 8.1 (3) of the *Evidence Act*).

⁹ Volume 2 of this report.

investigation and treatment if required. The guidelines also point out the necessity of being aware of legislation that might affect information exchange and limit discussion of some investigative information. Most health care institutions also have disclosure policies. Some are more cryptic than others. Some are very specific. The Ottawa Hospital, for example, specifically states that disclosure should include “the cause of the event, if known.”

It would be naïve to believe that disclosure has gained universal support in health care. In *Legal Liability of Doctors and Hospitals in Canada*,¹⁰ the authors examine another perspective:

There is, of course, a concern among some practitioners that disclosure of medical error may simply increase the likelihood of their being sued by the patient, but in fact the empirical evidence is to the contrary. Recent studies in the United States have shown that hospitals that implement an active policy of error disclosure actually experience a reduction in the incidence of malpractice litigation. Conversely, studies also show that patients who are not told about an error, and who later discover it, are much more likely to sue the physician or hospital. These findings are consistent with the research on the factors that influence patients in deciding to sue their physician. In particular, they are consistent with the findings that lack of communications, and a sense of betrayal or dishonesty, play a significant role in influencing patients to sue.¹¹

In my opinion, disclosure is now firmly entrenched in health care. There are still questions to be resolved. The common law sometimes moves slowly, but it is unlikely that the patients’ right to disclosure will be lessened. Rather, it is more likely this right will be expanded. It is, therefore, necessary to examine in a more balanced way the requirement for section 8.1 of the *Evidence Act* and what steps, if any, are required to reinforce disclosure of adverse events.

Those who followed the events related to the Commission may remember that it was the decision of Justice Dymond of the Supreme Court of Newfoundland and Labrador that determined the Commission

¹⁰ E. Picard and G.B. Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 4th ed. (Toronto: Thompson Carswell, 2007): p. 208.

¹¹ See: Sherry Espin, “Examining Disclosure Options” (Volume 2 of this report), for a comparison of a number of approaches.

could publish the reports of Dr. Banerjee and Ms. Wegrynowski, and, equally important, could have both appear as witnesses. Eastern Health had claimed that the reports were protected by the *Evidence Act* and by a common law privilege. Eastern Health had been prepared to provide copies of the report to the Commission¹², but only on the basis that neither the authors nor anyone else be examined on the contents and the reports could not be made public. My view was that to accede to that request would seriously undermine the credibility of the Inquiry process. How could the public have confidence in a process that would have kept private two of the most important pieces of evidence regarding the causes of the problem?

In the final analysis, Justice Dymond determined that the reports in question were not peer review reports, nor quality assurance reports under the *Evidence Act*, nor were they privileged under the common law. Consequently, he did not have to delve into the meaning of section 8.1 of the *Evidence Act*, nor the exemption under the *Public Inquiries Act, 2006*, SNL 2006, c. P-38.1. However, Justice Dymond opined that the language in s. 12(1) and s. 12(3) of the *Public Inquiries Act, 2006* is ambiguous. It is doubtful that in the future any regional health authority will ignore the prerequisites of the *Evidence Act* for a peer review or quality assurance report.

I would recommend that any ambiguity in section 12 of the *Public Inquiries Act, 2006* be resolved in favour of permitting a Commission of Inquiry access to the documents and unrestricted examination of the authors of any documents. In my opinion, if this Commission had not been given access to the reports of Dr. Banerjee and Ms. Wegrynowski and had not been able to examine them both, it would have been very difficult to answer, in particular, the questions raised in the first two Terms of Reference. Commissions of Inquiry are rare; rarer still are those which look at health issues. Generally the issues that demand such an approach are of great importance to the public and the health care system. It is difficult enough for a Commission to try to reconstruct

¹² In fact, copies of the reports were provided to the Commission in the fall of 2007, but with the agreement that if the Commission wished to examine the authors, Eastern Health would have the opportunity to have the question resolved by the Court.

events that may have occurred years before, but to deny it access to vital information would be to undermine the *raison d'être* of the Commission.

The *Report of the Task Force on Adverse Health Events*¹³ includes a summary of the arguments for the retention of an exemption under the *Public Inquiries Act 2006* and those for removal of the exemption. The statement that doctors are not participating in any reviews until the “gap” created by the *Public Inquiries Act, 2006* is filled must be addressed. The import of that statement is astounding. Had such a position been taken in 2005, it would have meant that doctors would have refused to assist in the examination of the ER/PR problem (to determine its cause and thereby assure that future testing was as accurate as possible), because of the chance that they might be called to give evidence at a public inquiry. What is just as troubling is the idea that a physician would refuse to participate in patient safety efforts because there is a very small chance that a public inquiry might be called related to those matters. Surely, that would run counter to every principle of medicine.

Some may say that the evidence could have been obtained in any event through another source. That might be true if it were one of those cases where A placed the medication on the wrong shelf and B, assuming it was the medication that was usually stored there, without checking, administered the medication. Here, because of the nature of the subject matter being investigated, it would have been extremely difficult to reconstruct events without Dr. Banerjee’s and Ms. Wegrynowski’s opinions and observations. Ms. Wegrynowski, an independent witness, was able to visit the laboratory and evaluate the protocols in 2005. It is a different place in 2008. Dr. Banerjee was able to talk to pathologists in 2005. Their memories of events relevant to the examination of the problem were clearer in 2005 than in 2008. The source of the best evidence is the reports of Ms. Wegrynowski and Dr. Banerjee. I should also add that neither Dr. Banerjee nor Ms. Wegrynowski lives in Newfoundland and Labrador. They could not, therefore, be required by law to assist the Commission. They both did so fully and without hesitation. I am extremely grateful for their assistance. I am reluctant to

¹³ St. John’s, Newfoundland and Labrador: QP, 2008.

conclude that their counterparts who live in this province would have approached the task differently.

I have suggested that any conflict between s. 8.1 of the *Evidence Act* and s. 12 of the *Public Inquiries Act, 2006* be resolved in favour of permitting Commissions of Inquiry to have access to peer review and quality assurance reports. In my view, however, the question has to be asked whether s. 8.1 of the *Evidence Act* is necessary at all. The underlying policy of the *Evidence Act* prohibition is suspect. Others who deal with safety issues do not have this protection. Pilots are an obvious example of persons whose profession requires them to make decisions affecting the safety of others. They are required to provide information to authorities in the interest of public safety, the opposite approach to the one taken in the *Evidence Act*. However, merely to repeal the section would not assist. as one would then be faced with the common law privilege.

The wording of s. 8.1 is ambiguous and certainly at odds with some of the practices described by Ms. Predham. A complete review of the section is warranted on that basis alone, but an equally compelling reason is the need to examine the legislation in light of other competing policy considerations. If there were a Law Reform Commission in this province, I would recommend that the issue be examined by that body so that the policy considerations could be fully aired. My own view is that there must be amendments to s. 8.1 of the *Evidence Act*.

Further, in my opinion, disclosure to patients must include, among other things, an explanation of why the adverse event occurred and what is being done to ensure that a similar event does not occur in the future. If there is a peer review or quality assurance report respecting the adverse event, those reports must be provided to the patient upon request. Openness and transparency demand no less. I recognize that such disclosure may not be possible at the first disclosure meeting, but it must be done. The peer review or quality assurance report may have the names of the individuals who participated removed, prior to disclosure to the patient. I would also recommend that legislation be enacted to

entrench this right and give the right priority over any prohibition contained in s. 8.1 of the *Evidence Act*.

If the purpose of s. 8.1 is to prohibit production in a legal proceeding of information emanating from a quality assurance or peer review committee of the specified institutions, then the solution outlined above, of redacting names, should not undermine the purpose of the legislation.

At a minimum, s. 8.1(3) should be amended. As the legislation is currently worded, for example, recommendations and information of peer review committee are prohibited from being disclosed in the circumstances specified under the legislation. Unless the interpretation of the legislation is a very narrow one, that could defeat patient safety. If one cannot reveal recommendations and information, which would include "facts," how does one prevent recurrence of adverse events, let alone disclose them to patients?

Some may say that there is no prohibition from revealing facts. Even if that were true, the nature of the matter under consideration in this Inquiry means that nearly every statement, including one that says that a result is positive or negative, is a statement of opinion. That there is poor fixation and that inadequate attention is being paid to internal controls are other examples. This is the kind of information that is necessary if one is going to tell a patient something about why the adverse event occurred and that must be done if possible. It is not enough to tell those patients who have had ER/PR results change from negative to positive what the new result is and how the treatment is to change. If the health system is to have any credibility, patients must be given an explanation for why the mistake occurred and what is being done to ensure that it will not happen in the future. If there was any recurring theme in what those witnesses who were patients said, it was that they wanted to be sure no one else had the experience they had had.

There is general recognition that patients to whom disclosure has been made may need what the CPSI Guidelines refer to as practical and emotional support as a result of disclosure of an adverse event. I agree

that this should be a part of policies on disclosure. In my opinion, however, it is equally important that those health care workers who are involved in the event have support available.

If the experience of those who dealt with the ER/PR problem is typical, and I have no reason to believe otherwise, physicians who do most of the disclosure under the current systems have no training in this aspect of patient care. Oncologists may be good at giving bad news, however, usually, they have no part to play in the events that give rise to the bad news. It is one thing to tell a patient that his or her condition has worsened. It is quite another for a physician to tell a patient that his or her condition has worsened because of something the physician did or failed to do. Physicians need training in performing this duty, and assistance should be provided where it is needed to help deal with the fact that one has harmed or failed to prevent harm to a patient.

Chapter Fourteen

DCIS and Retro-Converters

DCIS and Retro-Converters

During the investigation of the estrogen receptor/progesterone receptor (ER/PR) problem, two issues that were viewed as collateral emerged. The first involved a group of patients who became known as the ductal carcinoma in situ (DCIS) patients, the second a number of patients whose results for ER/PR went from positive to negative and who came to be known as the “retro-converters.” Neither identifier is really accurate. The two issues are unrelated but are conveniently dealt with under the one heading because in communications they were often paired.

DCIS

DCIS (ductal carcinoma in situ) is a non-invasive type of carcinoma of the breast. That is, the cancer is contained within the milk duct in which it is found. As Dr. Brendan Mullen explained it, in a DCIS case the malignant cells “haven’t broken through the basement membrane, and the concept is that if they haven’t broken through or invaded the adjacent stroma, then they will not metastasize.” Where there is minimal invasion, the diagnosis can remain DCIS. As a matter of policy, at Mount Sinai Hospital (Mount Sinai) ER/PR testing is not routinely done on DCIS cases. ER/PR testing would be done at Mount Sinai if a medical oncologist requested it. As part of the re-testing at Mount Sinai, an H & E slide would be produced from the block sent by Eastern Health. If Dr. Mullen diagnosed DCIS,¹ he would not do ER/PR testing on that tissue.

In Newfoundland and Labrador, the cases identified as DCIS by Dr. Mullen were, as he intended, subject to further review. For some, while the block sent to Mount Sinai did not indicate invasive carcinoma, other blocks from the same surgical specimen did suggest that there was

¹ Dr. Mullen made it very clear that on the basis of one block he was not purporting to provide a final diagnosis. When he saw, on the H&E slide, what he diagnosed to be DCIS, he asked Dr. Cook to send for re-testing any other block(s) which might indicate invasive carcinoma. The first such request by Dr. Mullen occurred on September 28, 2005, in relation to three DCIS and one DCIS with microinvasion results.

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an invasive carcinoma. When this occurred, a block containing invasive carcinoma was sent to Mount Sinai, and it was then used for the ER/PR re-tests. That is, the ER/PR re-tests were completed for that patient but on a different block. In other cases, the initial diagnosis in Newfoundland and Labrador had been DCIS and Dr. Mullen's work confirmed that diagnosis. Those cases were not ever re-tested for ER/PR. In still other cases, it was agreed that there had been an error in the original diagnosis. That is, the patients had been initially diagnosed with invasive cancer but the diagnosis should have been DCIS. Those cases were not re-tested. So then, what was within the Group called "the DCIS cases" cannot be taken to be cases for which the final diagnosis was DCIS, but only cases where, on first examination at Mount Sinai, Dr. Mullen reported that the one block from a particular surgical specimen he received from Newfoundland and Labrador suggested a diagnosis of DCIS.

Initially, when blocks were gathered to be sent to Mount Sinai, the criterion was the result of the ER test. No attention was paid to the diagnosis. After a period of time, because Dr. Mullen was not doing ER/PR testing on DCIS cases and because of a November 17, 2005, direction from the Panel, DCIS cases were not sent for re-testing, except in special circumstances. One such special circumstance was a December 1, 2005, request by Ms. Janet Henley-Andrews.

Janet Henley-Andrews: a DCIS Patient Tested for the First Time

Ms. Janet Henley-Andrews of St. John's was diagnosed with DCIS in 1997 and again in 2001. At the time of each diagnosis, anti-hormonal treatment was not discussed. As early as 1997, she was concerned about a lack of information and detail as well as a lack of reporting consistency in her pathology reports.

On November 7, 2005, Ms. Henley-Andrews contacted Eastern Health, requesting that her tissue sample be sent to Mount Sinai for testing. She knew she had not been tested for ER/PR because she had been diagnosed as DCIS, but she asked that her sample be tested during the ER/PR review. She spoke with Ms. Nancy Parsons, who then contacted Dr. Cook and passed along the request. Dr. Cook arranged for

her sample to be sent to Mount Sinai for testing. Ms. Henley-Andrews understood that her sample had been sent for testing but she did not hear anything from Eastern Health as to the results.

After hearing media reports that everyone who had been re-tested had been contacted, she again called Eastern Health. This time she was told that her sample had not been sent for testing. She was disappointed. This information was in fact incorrect: a tissue sample from Ms. Henley-Andrews' first surgery in 1997 was tested at Mount Sinai on November 16, 2005, shortly after she had made the first phone call to Eastern Health. The test was positive for both ER and PR. Ms. Henley-Andrews remained unaware that this test had been done until a meeting with Commission Counsel in February 2008.

Ms. Henley-Andrews' case came before the Panel for review on December 1, 2005. Notes of that meeting refer to her having DCIS. No panel letter was to be written and there is no course of action noted as to how Ms. Henley-Andrews was to receive the results of her test.

On March 6, 2008, Mr. Robert Thompson wrote to Ms. Louise Jones, seeking confirmation information about patients who had no original ER/PR test done in this province but who had had a test done at Mount Sinai. Ms. Henley-Andrews was one of the patients listed by Mr. Thompson. Ms. Jones gave Mr. Thompson's letter to Ms. Pat Pilgrim to respond to. The next day, Ms. Pilgrim replied to Mr. Thompson. In her response she stated that Ms. Henley-Andrews "was never tested for ER/PR as she was diagnosed with DCIS. This specimen was tested on her request and was disclosed to the patient in September, 2005." This is clearly an error. Ms. Henley-Andrews could not have been told the result of her test in September 2005; she was not tested until November 16, 2005.

DCIS: Testing for ER/PR

During the Inquiry hearings, a draft of the Eastern Health Clinical Practice Guidelines in Oncology-Breast Cancer was referred to. Dr. Joy McCarthy, an oncologist, stated that the following was merely a written

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clarification of the practice that had been operative at the Cancer Centre for some time:

DCIS/LCIS

Question: What is the role of Tamoxifen in the management of DCIS/LCIS?

Target Population: These recommendations apply to women with DCIS.
Recommendations and Supporting Evidence

These patients are generally referred by their surgeons and assessed by medical oncology, but have commonly been seen by radiation oncologists as well when a discussion regarding breast radiation is required. During the consultation, a discussion will ensue regarding the individual need for hormonal manipulation with each patient. Presently, it is unclear whether or not testing for estrogen and progesterone receptors should be performed routinely on DCIS/LCIS specimens. The group recommended that testing should not be performed on LCIS, since 99% are known to be estrogen and progesterone receptor positive. Currently, testing for hormone receptors status on LCIS/DCIS specimens is not standard in most centres in the country, and there is no evidence to suggest that knowing this result will affect the outcome. Therefore, the group has decided to not recommend carrying out routine receptor testing on DCIS. However, if an individual physician requests it, the pathology department will provide testing on a case by case basis following referral.

The oncologist will discuss the treatment option of Tamoxifen with those patients deemed to be candidates, especially those with high grade disease. Patients with low or moderate grade disease including those under the age of 50 should be considered for Tamoxifen. Patients who have undergone bilateral mastectomies do not require Tamoxifen. Those who have undergone a unilateral mastectomy could derive a small benefit for the remaining breast, thus a discussion with the patient should include the potential thromboembolic and endometrial carcinoma risks associated with Tamoxifen.²

In the United States it appears that the issue is one of some debate, with different institutions and individual physicians taking different positions on whether ER/PR testing should be routinely done for DCIS patients.

The current research cannot be said to dictate one particular view, and consequently a clinical decision not to automatically do ER/PR testing on all DCIS patients is a reasonable one.

² Exhibit P-2601, p. 5.

Within Eastern Health there was a great deal of procrastination concerning the DCIS cases. No one seemed to want to take responsibility for them. In part, the problem stemmed from the fact that for some cases there were changes in diagnosis. The Eastern Health pathologists doing the reviews questioned their authority to change a diagnosis made by another pathologist, particularly if that pathologist did not work for Eastern Health. Some consideration was given to having Dr. Robert Williams direct in writing that a review of DCIS cases be done. Letters were drafted for his signature, and there was discussion about the appropriate wording. Once again, this activity was directed at merely providing written authority for action that had already taken place. In the end, the other regional health authorities were contacted and asked if they wished to have Eastern Health review their DCIS cases or do the reviews themselves. In that way the authorization for the DCIS reviews by Eastern Health would come from the appropriate regional health authority.

Ms. Patricia Pilgrim's view was that each regional health authority was to do its own reviews, to determine the original diagnosis and, if necessary, to try to resolve any difference in opinion. In fact, Eastern Health was very much involved in most, if not all, of these reviews. The more frequent scenario was that Dr. Beverley Carter, Dr. Donald Cook, or Dr. Nebojsa Denic of Eastern Health would review the cases first. Some regions accepted their conclusions. Western Health's pathologists wanted to review the cases themselves before any final determination as to a change in diagnosis was made.

One might think that it would be a relatively simple exercise to determine how many of these patients there were, how many were finally confirmed to be DCIS, and what was communicated to these patients. That proved not to be the case. I shall not review the whole convoluted story of the number of DCIS patients and how their cases were eventually all dealt with. I note that both the Newfoundland and Labrador Centre for Health Information (NLCHI) and employees of Eastern Health spend a great deal of time trying to resolve questions about these patients, including whether all their cases had been reviewed and all had been contacted. That effort, Ms. Pilgrim said, only finally

concluded in September, 2008. In fact, a final review of the DCIS cases conducted by Dr. Meghan Walsh of Eastern Health was concluded only on February 10, 2009.³ What follows is a synopsis of their story.

By February 22, 2006, it appears that Dr. Mullen had identified a total of 57 surgical specimen blocks as either DCIS or NT (no tumour). On that day, Ms. Heather Predham provided a memo to Dr. Williams. Ms. Predham understood that the information contained in the memo would be distributed to the Board of Trustees of Eastern Health. In that memo, Ms. Predham referred to 55 patients who had been reported by Mount Sinai as either DCIS or NT. The difference between 55 and 57 may be attributable to two DCIS patients having been reported by Dr. Mullen as ER 0%, PR 0%, or possibly by two patients having been re-tested twice. In any case, on February 23, 2006, the Panel made a decision regarding how these patients were to be treated. If the original diagnosis in Newfoundland and Labrador had been DCIS, the case would not be reviewed by the Panel. If the patient came from outside Eastern Health's area, the appropriate region would be notified. All DCIS or NT cases that had not been reviewed as of that date would be held until all of the other cases had been dealt with by the Panel.

The patients who were confirmed DCIS were not initially told about Dr. Mullen's opinion because it did not affect their treatment and because, in Eastern Health's view, the cases should not have been sent to Mount Sinai in the first place. This approach did not change until the fall of 2007, after the work of NLCHI began, and it was decided that patients who were confirmed DCIS would be notified. It should be noted,

³ Dr. Walsh's February 10, 2009, report states: the number of DCIS patients is 54; the actual number of patients confirmed as DCIS is 30; of the 15 patients who had their initial diagnosis of invasive carcinoma confirmed on review of additional tissue blocks, five had a change from negative to positive following re-testing at Mount Sinai of additional blocks; nine patients were determined to have been misdiagnosed, of whom five originally diagnosed with invasive ductal carcinoma had it changed to DCIS following review, two had their original diagnosis changed from DCIS to another tumour category, one who had insufficient tissue for re-testing and for whom Eastern Health concluded invasive ductal carcinoma was the diagnosis, and the final patient, who had a second block categorized by Mount Sinai as "no malignancy."

however, that in the summer of 2008 there were still DCIS patients who had not been notified they had been part of the ER/PR review process.

By November 16, 2006, Ms. Predham was reporting to Dr. Oscar Howell that 52 patients fell into the category of "Confirmed DCIS"⁴ and four DCIS patients had required follow-up.

For the four DCIS patients who in 2006 were identified to have a change in diagnosis, the decision by the Panel was that there would be meetings with each of them to disclose the situation. Panel letters would not be done for them. While the DCIS cases were known in February 2006 to be an issue that had to be addressed, disclosure meetings with three of those four patients did not take place until July 2006.

On July 12, 2006, Dr. Denic, clinical chief, Laboratory Medicine; Dr. Kara Laing, clinical chief, Cancer Care Program; and Ms. Nancy Parsons, patient relations officer, met separately with three of the patients who had been incorrectly diagnosed. The first had been initially reported as having invasive cancer when the correct diagnosis was DCIS, which Dr. Denic described to her as a pre-cancerous lesion. The explanation given the second patient was less straightforward, as the ultimate diagnosis was less clear. However, Dr. Denic did tell her that she might have received chemotherapy that she did not need. The third patient was told that there had been an error when she was told that she had invasive carcinoma.

One of those three patients, during her disclosure meeting, asked for a written summary of what had been said. The patient was told by Dr. Denic and Dr. Laing that she would be provided with a written summary of the meeting. Indeed, the Commission was advised that it was not uncommon that such a request be made after a disclosure or that a written summary of the information be provided. Ms. Parsons, who had taken notes during the meetings, drafted a letter containing a summary of what had been said to the patient. Ms. Parsons then sent the draft

⁴ The use of the adjective "confirmed" is inaccurate here. Of the blocks noted by Dr. Mullen to be DCIS, 52 were not in the final analysis confirmed to be DCIS.

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summary to Dr. Laing. Dr. Laing advised Ms. Parsons the summary was fine. As Dr. Denic was on vacation, Ms. Parsons, on the instructions of Ms. Predham, sent the draft to Dr. Daniel Fontaine, who was filling in for Dr. Denic as clinical chief. Dr. Fontaine made some minor changes and approved the draft. The draft letter was a simply worded, clear statement of what had occurred in the meeting, based on Ms. Parsons' notes. When Ms. Parsons advised Ms. Predham that she was going to send the letter, Ms. Predham instructed Ms. Parsons to seek a legal opinion as to whether it was "wise" to do so.⁵ Ms. Parsons recalled speaking to Mr. Daniel Boone on the subject, but came away from the conversation not confident that she had an accurate understanding of the recommendations or the suggestions. Ms. Parsons then sought the advice of Ms. Predham. She recalled that they never did complete an acceptable version of the letter for the patient. Ms. Parsons did not tell Dr. Laing or Dr. Denic that the summary had not been sent to the patient. While Ms. Predham's testimony about the summary was to the effect that she thought it was being handled, Ms. Parsons clearly felt she was not free to send the summary. She eventually told the patient that she had no authority to send the summary to her. Since both Dr. Laing and Dr. Fontaine had agreed to the form of the summary, Ms. Parsons' reluctance could have only arisen out of something said to her by the solicitors for the Health Insurance Reciprocal of Canada (HIROC) or by Ms. Predham, the risk manager.

In the case of the fourth DCIS patient, a year and a half elapsed between Dr. Mullen's email to Eastern Health, in which he communicated a diagnosis of DCIS, and the meeting at which this change was disclosed to the patient. This patient did not come before the Panel for consideration until September 7, 2006. At that time, the Panel noted that Eastern Health laboratory personnel had confirmed that Dr. Mullen's DCIS diagnosis was correct - the original 1998 diagnosis of invasive carcinoma having been incorrect - and that the patient should

⁵ This can be compared to the situation in July 2005, when a copy of a proposed letter to be sent to patients was sent to HIROC's solicitors. Ms. Predham explained that because the draft July 2005 letter was going to a large group of people, you have the potential of saying something that would inadvertently compromise a case, so you run it by a lawyer just to get their opinion.

therefore be met with and informed about the changed diagnosis, although the Panel noted the patient required no change of treatment. The Panel also noted no letter was to be sent in relation to this case. The disclosure meeting with this patient only finally occurred on July 11, 2007, when Dr. Denic, Dr. Laing, and Ms. Parsons met with the patient and a relative of the patient.

An affidavit of Ms. Predham, dated February 9, 2007, was filed in the class action proceeding. In that affidavit, Ms. Predham stated that of the cases sent to Mount Sinai, there were “52 patients determined to have ductal carcinoma in-situ, and therefore no form of treatment would have been recommended.”⁶ She added that among the 317 patients whose ER/PR test results were different, four patients now saw a change in their original diagnosis: this appears to be a reference to the four changed diagnoses having to do with DCIS. The October 2008 version of the NLCHI database provided to the Commission lists 53 patients initially reported by Dr. Mullen as DCIS; he reported on 55 DCIS surgical specimens.

Subsequent to the December 11, 2006, media technical briefing, additional DCIS patients were identified as having been originally misdiagnosed with invasive carcinoma. Efforts to ensure all the patients categorized as “DCIS” were properly dealt with continued well into the summer of 2008. In August 2008 Mr. Barry Dyer and Dr. Nash Denic were still meeting to “tackle the DCIS list.”⁷

Dr. Denic, in his testimony of September 12, 2008, recalled the four cases originally diagnosed with invasive carcinoma that had in fact been DCIS. He stated that four more cases have since been identified where the status changed from invasive carcinoma to DCIS or benign lesion. The latter four were not from Eastern Health. It would seem then that as

⁶ The draft Eastern Health Clinical Practice Guidelines in Oncology - Breast Cancer referred to earlier indicate that for some DCIS patients there may be treatment with tamoxifen.

⁷ Exhibit P-3457.

a by-product of the ER/PR testing a total of eight cases of misdiagnosed patients had been discovered as of September, 2008.⁸

In summary, Eastern Health reasoned that the DCIS patients should not be considered as part of the retrospective. This could only be based on the view that ER/PR tests should not have been run on DCIS patients. From the perspective of what had gone wrong in the testing, the decision to not re-test those who had been diagnosed as DCIS effectively eliminated from consideration a group of patients who met the re-test criterion set by Eastern Health. While there were 52 (or 54) DCIS patients, it must be remembered that after a certain point DCIS patients' blocks were not being sent to Mount Sinai. We do not know how many were eliminated by that decision. We do know that, in fact, a number of DCIS patients had ER/PR tests performed in the period between 1997 and 2005. In 2005, the Healthcare/Eastern Health policy on ER/PR testing for DCIS patients generally mirrored that of Mount Sinai. Prior to 2005, the situation in Newfoundland and Labrador could vary from hospital to hospital or from pathologist to pathologist.

With 2 exceptions, there was no report of ER/PR results from Dr. Mullen whenever he determined the tissue in a block to be DCIS. Where the initial diagnosis from Newfoundland and Labrador had also been DCIS, in accordance with the plan, there would then be no ER/PR re-testing at Mount Sinai for that surgical specimen. Whether the patient's tumour tissue was DCIS did not interfere with the validity of any ER/PR test result. Any proper analysis of the ER/PR problem should have included re-testing of those DCIS patients for whom ER/PR tests had originally been done and the original result was ER negative. It must be remembered that when Dr. Mullen excluded DCIS from the retrospective he did not know the nature of the problem in Newfoundland and Labrador or the true purpose of the re-testing process.

The decision not to re-test the DCIS patients limited the number of ER negative cases that would be examined. Information based on those re-tests could partially have contributed, for example, to an analysis of

⁸ Dr. Meghan Walsh puts the number of DCIS patients with changed diagnosis at nine as of February 2009.

whether the incorrect negative ER results were more prevalent during a particular period, or for different pathologists or technologists, or with different equipment or antibodies.

Retro-Converters

The story of the retro-converters is even a little more complicated, in part because of terminology. By way of refresher: when it is being used to determine options for treatment, a positive result on an ER or PR test is a good thing. If the results are negative, the patient will generally not be considered for anti-hormonal therapy. To pathologists, an ER or PR test is positive if the positivity of tumour cells is 1% or greater. To oncologists, a certain percentage of positivity must be present before a result is considered “clinically positive.” The percentage that signifies clinical positivity has varied over the years and from place to place. Between 1997 and 2007, the cut-off for anti-hormonal treatment in Newfoundland and Labrador varied from 30% positivity to 10%. Today, under certain circumstances, 1% is considered to be sufficient to warrant considering the use of anti-hormonal therapy. So, in 1999 an oncologist who had been advised that ER positivity was 25% would likely tell a patient that the test result was negative because the result was less than 30%. To further complicate matters, pathologists often reported results based on clinical positivity. In other words, the pathologist’s opinion was stated using clinical positivity as the standard. Sometimes percentage figures would be included in the report; sometimes the report would merely say “negative” or “positive.” Parenthetically, aside from the original memo by Dr. Mahmoud Khalifa to pathologists, no one was able to point to any written protocol or communication between or among pathologists and oncologists in Newfoundland and Labrador in which the percentage considered to be clinically positive was recorded. The potential for miscommunication when the pathologist’s report merely says positive or negative is obvious. Eastern Health officials pointed on a number of occasions to the problem of turnover in pathologists. It was only in the early 2000s that the composition of the group of medical oncologists in the province stabilized. Those circumstances made it all the more critical that the meaning of the words “positive” and “negative” in the context of ER/PR testing be clearly stated in writing so that both

oncologists and pathologists would be certain as to the meaning of those words as they appeared in pathology reports.

The term “retro-converter” was coined within Eastern Health, just as “conversion” had been. A conversion was a change in ER result from clinically negative on original testing to clinically positive on re-testing. In its submissions to the Commission, Eastern Health stated that retro-converters were patients who had had their results change from being considered clinically positive to clinically negative. Counsel for Eastern Health then added the following explanation:

Patients whose results had been considered positive using the definition of greater than 30% staining before January 1, 2001 and greater than 10% staining after that date, had not been selected for retesting. The cases that fell into the “retro-converter” category were ones that actually had “negative” original test scores of 30% or less before January 1, 2001 or 10% or less after that date, but had been treated with hormonal therapy as if they had been positive. When retested, their test results were 0% for ER and 0% PR, so that there was no longer any indication for hormonal treatment.⁹

In her testimony Ms. Pilgrim stated that she was unsure as to whether a patient’s having received (or not received) anti-hormonal treatment was a factor in determining if he or she was a retro-converter. Mr. Gulliver, on the other hand, believed that a change of treatment is what determined who would be placed on the list of retro-conversions. Ms. Predham stated that she understood that whether one was considered to be a retro-converter was determined not by clinical negativity but by the pathologist’s view. As Ms. Predham explained it, a person who had been originally 30% positive for ER and on re-test became 2% positive would not be a retro-converter because there was on re-test still some positivity. In other words, for a patient to be classed as a retro-converter the re-test had to go to zero, or less than 1 percent positivity. Later that same day, in describing who had been on the final list of four retro-converters, Ms. Predham stated that they were the only four for whom there was an impact of treatment. This is consistent with the position taken by Ms. Pilgrim that deceased patients could not be among the retro-converters, there being no change of treatment possible

⁹ Submission of Eastern Health, para. 455.

for them. It is evident that within Eastern Health there was no consensus on the definition of a "retro-converter."

Another term that arises in the discussion of retro-converters is "false positive." A false positive is a result that displays a level of positivity of 1% or more when in fact there is less than 1% positivity in tumour cells. False positive and false negative are terms that appear in the literature on testing.

It seems then that for some persons at Eastern Health, retro-converters were patients who had had false positive results for ER and who, after re-testing, had a change in treatment. That definition still would not reduce the retro-converters to four because, as Ms. Predham acknowledged, the Panel on January 12, 2006, dealt with a patient the Panel considered to have been a false positive for ER, and who as a result of re-testing had had her anti-hormonal treatment discontinued by Dr. Joy McCarthy - and yet the patient was not included in the official list of four retro-converters.

It appears that the idea that there might be retro-converters was first considered in January 2006, when two such cases were identified by Ms. Predham, though there had been at least one such case identified in the fall of 2005. As it turned out, the two January 2006 potential cases were not false positive cases. However, there were others to come.

Handwritten notes made by Dr. Cook in the early spring of 2006 indicate that he and Dr. Carter had identified true nuclear staining on the original ER and/or PR slides for some of the cases that on re-testing Mount Sinai had reported as ER 0% and PR 0%.

On May 15, 2006, Dr. Cook produced a list of 17 "retro-converters." The list contained the names and surgical numbers for those patients. Ms. Predham added another five surgical numbers to that list, though the list still represented only 18 patients, before taking it to Dr. Laing. These 18 patients had gone from clinically positive to negative. After the consultation between Dr. Laing and Ms. Predham and a teleconference involving Dr. Denic, the list was reduced to eight surgical

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specimens for seven patients. The basis upon which cases were eliminated could not be provided by either Dr. Laing or Ms. Predham, nor is it evident from the data. It does appear that anyone who had already been through the Panel process was deleted from the list, though not everyone who was deleted from the list had by then been considered by the Panel. The seven patients' tissue samples were then re-tested again at Mount Sinai. One additional person was removed from the list on the basis of the second re-test results from Mount Sinai. That left six patients. Officially, the number of retro-converters was generally stated in exhibits and said by witnesses to be four. How the total went from six to four is not clear. It was Dr. Denic's opinion that the four "official retro-converters" were caused by a pathologist having, in error, reported background staining as nuclear staining rather than because a slide had been produced with false nuclear staining. There were numerous reports, memos, and emails produced over the years in which the number of retro-converters is consistently said to be four.

Communication with those patients Eastern Health considered to be retro-converters was delayed. Initial plans in the summer of 2006 to carry out such disclosures were put off because of concerns within Eastern Health about adverse media publicity related to misdiagnosis of DCIS patients. The Panel in September 2006 decided in respect of retro-converter patients to use a panel letter to communicate its treatment recommendations, rather than the face-to-face meetings used in the cases of DCIS patients.

Ms. Nancy Parsons' recollections of her contacts with patients and their families included one in which the brother of a deceased patient, who had been a retro-converter, called often looking for information. Because his sister's test results had changed, Ms. Parsons did not believe that she could respond to his questions. Ten months passed from the initial contact with Ms. Parsons before a meeting occurred with the patient's brother. Like the DCIS patients, the retro-converters were not a priority for Eastern Health.

In his testimony Dr. Denic said that in 2008 he had, at the request of patients whose original ER result had been positive, re-tested 10. They

all remained positive. Since the end of the Inquiry hearings, Eastern Health has advised the Commission that another positive ER patient who asked to be re-tested had in mid-October 2008 changed from positive to negative. As with the earlier four, Dr. Denic has reported that this false positive could be explained by a misinterpretation by the original pathologist of background staining rather than false nuclear staining of tumour cells.

Ms. Predham agreed that the number of retro-converters “if you go by taken off tamoxifen” is four,¹⁰ “but from a retro converter from a true laboratory perspective on what really is a false positive, in other words, I don’t have any idea what the number is.” She added that an analysis of that issue was underway, but she did not know its status as she was not involved.¹¹

The criterion for re-testing was clinically negative ER. A number of patients who were re-tested because they had clinically negative ER results had originally positive PR results. For example, if the patient’s results in 1999 were ER 25% positivity and PR 40% positivity, that would have triggered a re-test in 2005. In such cases, the original treatment was often given based on positivity for PR. If that patient’s results on re-testing remained ER negative but became PR negative, the case would go to the Panel because a treatment change might be required. However, going from 40% PR positivity to 0% was not termed a retro-conversion. Dr. Laing confirmed that cases of this nature occurred.

The evidence of Dr. Donald MacDonald and Dr. Reza Alaghebandan, both of NLCHI, demonstrates both the difficulties in using the data coming out of the re-testing and, in light of the failure to re-test the positives, the problems with any attempt to perform an analysis of that data. I agree with the decision of Eastern Health to track

¹⁰ However, on cross-examination by counsel for The Canadian Cancer Society, Newfoundland and Labrador Division, Ms. Predham also stated that at least one other patient should have been included in that list.

¹¹ In an email communication dated February 16, 2009, Mr. Daniel Simmons, counsel for Eastern Health, advised the Commission that there had not been report prepared by Eastern Health in relation to any analysis of the retro-converter cases.

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the number of patients whose treatment required change, though for reasons enunciated elsewhere that was not properly done. The impact of the ER/PR problem on patient care is an important part of the story. However, the ER/PR problem is also a quality issue and quantification of the number of patients with a change in treatment does not assist in identification and resolution of the problems with testing, which are critical to future patient care. Because of the number of variables in the decision to prescribe anti-hormonal drugs, there is no direct relationship between treatment change and the validity of laboratory testing. Dr. Laing's evidence about the cases that were called "saved by the PRs" illustrates the point. Those were the cases where the original results were ER negative, but the patient had been prescribed tamoxifen or some other anti-hormonal drug on the basis of PR positivity. For a number of those cases, the original ER result was incorrect. It should have been positive. However, because the patient had been originally treated as positive on the basis of the PR result, no change in treatment was warranted for the patient.

At its core, the ER/PR problem raised questions about the validity of the practices and procedures related to ER/PR testing, the slides produced by the laboratory at the General Hospital, and the interpretations of those slides. To resolve those questions, Eastern Health should have collected and correlated the data relative to the validity of the testing. In that process, decisions about patient care are not central to the analysis. It is accuracy of results that is crucial. It would matter that a negative ER result was incorrect, even if, in that case, the treatment for the patient was no different than it would have been had the result been positive. The objective is to achieve the greatest accuracy possible in testing. It would matter that an ER of 0% had originally been reported as an ER of 5%, because a true negative should not be staining positive, though clinically a 10% cut off would result in the same treatment. Eastern Health chose to do its analysis on the basis of patient treatment outcome. Consequently, decisions about the collection of data – decisions that would permit a proper scientific analysis of the changes in result – were not made. Having failed to examine properly the number and nature of the testing errors, Eastern Health can have no credibility when

it argues that one cannot relate the weaknesses identified by the experts to the changed test results.

I would add that this weakness in Eastern Health's data regarding re-testing is not cured by the work of NLCHI. Dr. Alaghebandan of NLCHI was clear. NLCHI was asked to answer two questions: whether everyone who received a negative ER test result between 1997 and 2005 was re-tested at Mount Sinai, and whether everyone who was re-tested was contacted about the re-test results. He said that the NLCHI report was a descriptive report, "not an explanatory or analytical report. It can't say why we have this number, it can't say what are the factors involved with this figure or other figure."¹²

Re-testing the positives

Consideration must be given to whether there should be re-testing of the ER positives. Dr. Reza and Dr. MacDonald agreed that, at present, there is just not enough data to come to any conclusions about the issue of retro-converters or "false positives." Dr. MacDonald's view was that the approximately 20 original ER positive tests that had been included in the database was a biased sample. The small number of re-tests done at the request of patients would not change that. As to the idea of doing a sample test to determine whether the rate of false positives is outside that indicated in the literature, Dr. MacDonald was of the view that with 2000¹³ original positive results, one would require a proper sample size of 300 to 400 patients before one could have any confidence in the results being statistically significant.

This is not a decision to be taken lightly. Dr. Denic advised the Commission that it would take approximately three to four years to do the re-tests and during that time the laboratory at the General Hospital probably would not be able to sustain the service they offer. As for a review of the original slides to determine if there were other cases like the retro-converters where there was misreading of background staining

¹² Transcript of testimony, Dr. Reza Alaghebandan, October 23, 2008, p. 279.

¹³ Dr. Denic agreed that it would be in the neighborhood of 1500 cases, Transcript of testimony, Dr. Nebojsa Denic, September 15, 2008, p. 97.

as nuclear staining, Dr. Denic said that would require approximately 10 minutes per slide. Clearly either of these would be a major undertaking requiring a significant resource allocation.

When asked why the cases with positive ER results were not retested, Eastern Health witnesses responded that the literature does not support taking this action. In its submission to this Commission, Eastern Health said:

When the decision was made in August 2005 to retest, the consensus view among those involved, including Dr. Cook and Dr. Laing was that the problem with ER/PR tests was false negatives, not false positives, and that retesting of positive results was not necessary. The medical literature, including many of the publications referred to in this submission, identify worldwide problems with false negative ER/PR results, but there is no similar body of literature documenting false positive results.¹⁴

In her testimony, Dr. Laing's explanation was as follows:

There were very few of those that were identified by us as part of the tumour panel. And when we examined those patients, these were patients who had been described as having very weak staining and the attending oncologist had looked at those patients and had made a decision to offer them hormonal therapy based on that. Some of them had a cutoff that was higher than what we were using at the time. For example, it might have said there was very weak staining in 15 percent of the cells, and that was acted upon as a reason for treatment. The pathologists involved in this took out those original slides and reviewed them. ... but I do recall having conversations with them after to say when I went back and looked at those slides, I perhaps wouldn't have called that positive. They felt that the staining was more background staining than true stain of the cells. And I can assure you that this is an issue that we had thought about, that we thought about at the time, that we have had subsequent meetings about and that we have all put our heads together on to ask the very important question that you have asked, should we go back and retest all the positives. And because that was such a low number and because it had been in the people with very weak staining, we never felt that there was a signal or an indication strong enough that would warrant a review of all of the hormone receptor positive tests done over that time period.¹⁵

¹⁴ Submission of Eastern Health, para. 459.

¹⁵ Transcript of testimony, Dr. Kara Laing, September 10, 2008, pp. 53-54.

Dr. Laing said that there was no plan to re-test the positives. Ms. Pilgrim said the same thing during the Inquiry. However, Eastern Health was re-testing positive ER cases when requested to do so by the patient. Ms. Louise Jones, the acting CEO, in her testimony of April 30, 2008, stated that Eastern Health would re-test positive ER cases if patients requested that they do so. However, there had been no public announcements to that effect, nor had that information been placed on Eastern Health's website.

In paragraph 462 of its submission to the Commission, Eastern Health states:

Eastern Health is now in the process of reviewing that position. The questions being considered are:

- Whether the question can be addressed by reviewing the original test slides for interpretation errors; or
- Whether specimens would have to be retested; and
- In either case, whether a statistical sampling methodology can be used.

No definitive decision has been made.¹⁶

Dr. David Dabbs was asked about his experience with false positives. He had not seen a false positive hormone receptor result, other than something that was fixed primarily in alcohol. He added:

If a tissue is improperly fixed in formalin, ... the next three solutions on the tissue processor are alcohol. So if something is getting just a very minimal exposure to formalin, it's theoretically possible that one could obtain a false positive result, based on alcohol fixation. The only other incident that I can think of would be with over antigen retrieval giving a simulated nuclear expression of something which happens to be biotin. If you're using a certain - the ABC [avidin-biotin complex] - method, as the method for immunohistochemistry in that situation, but overall, that should be exceedingly rare.¹⁷

The same point regarding fixation alcohol was made in an interview attached to a Review Article: Recommendations for Improved Standardization of Immunohistochemistry. Dr. S. Badve states:

¹⁶ Submission of Eastern Health, para. 462.

¹⁷ Transcript of testimony, Dr. David Dabbs, September 16, 2008, p. 59.

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Standard processing protocols entail the use of alcohols after the tissue is fixed in formalin. Alcohol is also a fixative with relatively rapid penetration. So if unfixed tissues are “loaded” onto a processor, they are more likely to undergo significant “alcoholic” fixation which can lead to altered IHC and false positive results.¹⁸

Dr. Dabbs explained how one would know that over antigen retrieval has taken place:

Well, I think that a distinct clue would be if you’re running a proper negative control in which the primary antibody is replaced with anti serum from the animal of the primary antibody you’re using, because then you also are using the detection kit in there as well. So if you’re exposing that in the same manner with extreme antigen retrieval, you should get the same result in a negative control.¹⁹

He agreed that without external negative controls, detection of the problem would be very difficult. Dr. Dabbs confirmed that the concerns about over antigen retrieval would probably not apply if the peroxidase anti-peroxidase method was being used.

The subject of the possibility of false positive staining was also raised by Ms. Trish Wegrynowski in her report of May 2, 2006, entitled, *Quality Reassessment Review of the Immunohistochemistry Laboratory Health Care Corporation of St. John’s*. She recommended:

A policy must be established relating to the non-specific false positive staining associated with staining from endogenous biotin. This is critical as the Laboratory utilizes an avidin-biotin complex detection system.

Testing which requires pretreatments and heat induced epitope retrieval should be routinely blocked with avidin and biotin to avoid this issue.²⁰

Dr. Dabbs was, of course, talking about false positive results caused by nuclear staining that should not have occurred because the nuclei were not, in fact, positive for hormone receptors. There may also

¹⁸ Exhibit P-1767.

¹⁹ Transcript of testimony, Dr. David Dabbs, September 16, 2008, p. 226-227.

²⁰ Exhibit P-0048, p. 13.

be false positive results because the slide is incorrectly interpreted as showing nuclear staining. Dr. Denic expressed the view that the four “official” retro-converters were the latter. That is, he felt that background staining had, in error, been read as nuclear staining. Dr. Emina Torlakovic was of the view that a proper investigation of misinterpretation of background staining as positive nuclear staining would be to conduct a “wide audit” and review test results reported as positive in the past for the pathologist or pathologists in question. Dr. Dabbs said in such circumstances he would adopt a similar approach.

The evidence presented by Dr. Mullen, who did the retrospective study and reviewed a large number of the original slides from Newfoundland and Labrador, and that of Dr. Beverley Carter, Dr. Diponkar Banerjee, and Dr. Don Cook, all of whom examined a selection of ER cases from 1997 to 2005, was consistent on the subject of fixation. All noted fixation problems.

The fixation problems and the local use of avidin-biotin in ER/PR testing for a period of time, coupled with the fact that there were no negative controls run during the relevant period, lead me to the opinion that the generally low rate of false positive results referenced in the medical and scientific literature cannot here justify the decision not to re-test ER positive patients. In short, the reasons relied upon by Eastern Health to conclude that the incidence of false ER positive results is so low as to make re-testing unnecessary just do not hold up, given the identified problems.

Chapter Fifteen

The Deceased

The Deceased

From the beginning, it would have been clear to all involved with the re-testing plan that not all of the patients whose specimens would be re-tested would still be living. However, there was no clear statement or understanding of how these cases were to be handled. In mid-July 2005, when the plan was to have Dr. Beverley Carter do the re-testing using the Ventana Benchmarks, the description of the group to be tested at that point was all samples from 1997 to April 2004 (when Eastern Health began to use the Ventana Benchmarks), commencing with the negative samples. Dr. Robert Williams advised Mr. George Tilley that, as results could affect future treatment, the plan was to test the living first, then the deceased. Dr. Williams stated that the deceased were included because he felt that their relatives had a right to know the results. He also felt that was the consensus of the Group at the time. In Dr. Williams' notes from the August 10, 2005 meeting, the last entry reads: "decide on how we will address deceased people in terms of testing." There are also references in Dr. Williams' notes of July 12 and 14, 2005, to testing "all samples of living patients." There was, however, no clear understanding on the point. In the summer of 2005, there were those who thought that all patients would be re-tested, but the living first,¹ those that believed that only the living would be re-tested², and those who thought that the question of the re-testing of the deceased was not yet decided.³

The communications in August and September 2005 from Dr. Donald Cook to pathologists in the province varied on that issue, if it was addressed at all. Dr. Gary Baker, of Carbonear, understood that the

¹ Deborah Thomas-Pennell recorded this in a briefing note.

² Dr. McCarthy, the oncologist who dealt with the re-tests done by Dr. Carter, saw no point in pursuing the re-tests for the deceased, as the goal was to find people who required a treatment change.

³ Dr. Cook had told Dr. Gary Baker of Carbonear that the question of whether to test the deceased had not yet been decided.

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deceased were not to be re-tested.⁴ Dr. Barry Gallagher, of Gander, assumed everyone was being re-tested because he saw the exercise as “a laboratory test, first of all, to determine the effectiveness of the test, and the clinical implications and the treatment implications would be handled down the road.” On August 8, 2005, when advising pathologists in St. John’s about the re-test, Dr. Cook specified that the deceased would not be included in the re-testing at Mount Sinai. A similar message was given to Dr. Paul Neil of Western Health in September when he was instructed by Dr. Cook about gathering the patients’ blocks for Mount Sinai.⁵ Generally, then, when the deceased were identified in St. John’s, their blocks would not be sent to Mount Sinai but would be set aside. Some other regional health authorities proceeded as St. John’s was doing; others did not know about the instruction and included tissue specimens of deceased patients in those sent to Eastern Health for shipment to Mount Sinai. At Eastern Health there was no culling of blocks from other regional health authorities to exclude deceased patients. Consequently, deceased patients were included in the retrospective, particularly early in the process. It was not until 2007 that specimens of the patients who had been identified in St. John’s as deceased were sent for re-testing. As will be seen, that occurred only after Eastern Health was directed to re-test those patients. When deceased patients were re-tested, the results were put aside until “all the living [were] done.” Ms. Heather Predham took the position that the Panel did not knowingly talk about any deceased patients.

⁴ In August or September, 2007 Dr. Gary Baker checked. He checked one case from 1998 which he had reported to be positive (15-20%), and realized that it had not been sent for re-testing though it fit the September 6, 2005, criteria set out by Dr. Cook of 30% or less before 2001. Dr. Baker then checked further and discovered 10 such cases. In making the arrangements with Mr. Gulliver to have those patients re-tested, because of a casual comment by Mr. Gulliver, Dr. Baker also discovered that there had been a decision made to re-test the deceased patients. Carbonear had not in 2005 sent its deceased patients’ cases for re-testing as they had been advised in 2005 the deceased were not to be re-tested at that time. As a result, they added three or four deceased patients’ cases to the 10 that had been missed, and forwarded them all to the General Hospital.

⁵ Dr. Neil stated that he had used Meditech in Corner Brook to determine if a patient was alive or dead. However, this was an effective method only if the patient had died in an institution affiliated with Western Health.

As it turned out, the process of identifying the deceased was not an easy one. The data available within Eastern Health did not provide the answer for every case. It was initially thought that the Cancer Registry might provide assistance. It would show data such as MCP numbers, names, surgical specimen numbers, and whether the patient was alive or dead. However, when Eastern Health received information from the Cancer Registry in the summer of 2005, it was clear that there were gaps. Ms. Predham testified that the Cancer Registry had provided information on only about one half of the patients to be re-tested. However, there was a database that was not used. Dr. Donald MacDonald, of NLCHI, testified that the provincial mortality database could have been used to check whether specific patients were deceased. He confirmed "... it certainly would have been easily done if they had asked." Dr. MacDonald also added: "The database has been around for many years. We were not asked." ⁶

In summary, some regional health authorities tried to identify the deceased and put aside those cases until re-testing had been completed for the living patients. Because some regional health authorities purposely included deceased patients' blocks for re-testing and because the methods of determining who was dead were so flawed, it turned out that approximately 100 deceased patients' cases were sent to Mount Sinai for re-testing at the same time as the re-testing for the living patients was being done.

In Eastern Health's communications, not much attention was being given to the issue. Neither the public advertisement run in October 2005 by Eastern Health nor the letters to physicians and surgeons by Dr. Williams and Dr. Paul Gardiner respectively mentioned anything about re-testing the deceased. That does not mean that families were uninterested in the matter. On September 14, 2006, Ms. Susan Bonnell received an email from the husband of a deceased patient in which he threatens to go to the media if someone does not respond to him regarding his late wife's test results. He had, by then, requested the results on several occasions.

⁶ Transcript of testimony, Dr. Donald MacDonald, October 23, 2008, p. 141.

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Within the Department of Health and Community Services, Ms. Moira Hennessey, Assistant Deputy Minister, Board Services, understood from a meeting she attended on October 3, 2005, that the focus would be on the living. The re-testing for deceased patients would be done later. Departmental briefing notes around that time stated that there could be some potential litigation issues for the families of deceased patients, once the families were notified. On November 4, 2005, Ms. Predham sent an update to Ms. Hennessey regarding the situation at that time. She said that, as to the deceased (then 158), "arrangements will be made to notify family members once all results have been received."⁷ She noted that they knew some had died only because of having tried to contact them about the re-testing. This information was included in a briefing note prepared by the Department of Health and Community Services on November 7, 2005, and in a briefing note to the Minister on November 17, 2005.

Ethics Consult

In May 2006, attention turned to the question of what to do about the deceased patients. Eastern Health had received re-test results for approximately 100 of them over the previous nine months and Dr. Cook was uncertain about whether he should sign off on the reports in Meditech, as he had done for Eastern Health's living patients. He sought instructions from Dr. Williams and this spurred Dr. Williams to seek an ethics consult. Ms. Louise Jones, who arranged for Dr. Rick Singleton, Director of Pastoral Care and Ethics for Eastern Health, to conduct the ethics consult, recalled that at the time Eastern Health was not intending to have the balance of the deceased cases re-tested. Dr. Singleton was not asked to address that point in the ethics consult. Interestingly, both Dr. Joy McCarthy and Mr. Dan Boone believed, before the ethics consult meeting began, that one of the questions to be addressed was whether there should be re-testing of deceased patients.

Dr. Singleton arranged the meeting and acted as facilitator. Also attending the meeting on June 19, 2006, were Dr. Nebojsa Denic, Dr.

⁷ Exhibit P-0098.

Cook, Dr. McCarthy, Ms. Predham, Mr. Boone, and Dr. Natalie Bandrauk, intensivist and ethicist. Dr. Singleton's report stated, in part:

The problem with the results was rooted in the test procedures used in the time period from 1997- 2005. In 2005 samples known to have been processed for this batch of patients were forwarded to Mt. Sinai in Toronto for retesting at their lab. In the batch forwarded to Mt Sinai there were 101 samples from deceased patients, 19 of the retested samples produced results that may have resulted in a different care plan and treatment follow-up than that implemented based on the original test results.

Important facts to the history and understanding of this case include the following:

There were no mistakes or technical errors at the root of this problem;

It is impossible to know in any specific case if the outcome for any individual patient would have been different;

Intervention for post-menopausal women had positive impact by lengthening life in 47% of patients treated,

The main ethical issue in this case pertains to disclosure. There are several considerations regarding the duty to disclose, the right of families to be informed of results from the retesting at Mt. Sinai, and who should manage the disclosure processes.

The obligation to disclose the information to families is based, from an ethics perspective, on the negative right of families to the information about the deceased. A negative right respects the right of individuals or families to access information, but it does not oblige anyone to make direct contact with individuals or families to provide the information. The obligation to inform is different in this situation than if situations where a mistake had been made, where the information would make a difference or potential difference in the care plan or interventions of a patient.

While legally no one has the right to a deceased person's health record or other health information in the context of the Core Values of Eastern Health and in a spirit of good will it is appropriate that Eastern Health take reasonable steps to inform the community that this problem has occurred and that information is available. This can be done through local media and as part of the follow up from previous media coverage of the issue.

Access to the information or health record must be requested in writing. The request must come from the individual or individuals in line of priority to identify substitute decision-makers according to the Act Respecting Advance

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Health Care Directives and Substitute Decision-makers. The request would be handled according to the policies and practices pertaining to health records.

Contact with families ought to be managed mainly by the Risk Manager with the assistance of competent staff and the Corporate Communications Department. The ethics consultation had several recommendations in this regard.

1. A press release prepared as this matter is being resolved ought to mention that information pertaining to deceased patients may be available by contacting the appropriately designated office or number.
2. Efforts should be made to ensure information about the retested samples be presented by an individual competent to explain the matters to the family member.
3. If families of deceased patients whose samples have not been retested request the same information then it should be explained that the sample has not yet been retested and it will be retested, if that is the preference of the family, and that the retesting will be done at the site doing this testing procedure for Eastern Health when the request is made.⁸

All of those who attended, except Dr. Bandrauk, gave evidence at the Inquiry. All except Dr. Singleton and Dr. Bandrauk were intimately involved in some aspect of the ER/PR problem.

As is evident, the point raised by Dr. Cook, which was said to have caused the consult to take place, was not addressed in the report.⁹ There was discussion of the background, for the benefit of Dr. Bandrauk and Dr. Singleton. The characterization of the information gathered turned out to be critical to the advice given. The report stated that one of the important facts was “there were no mistakes or technical errors at the root of this problem.” Later in the report Dr. Singleton says: “The obligation to inform is different in this situation than [in] situations where a mistake had been made, where the information would make a difference or potential difference in the care plan or interventions of a patient.” The testimony of those witnesses who attended the consult leads me to conclude that at the meeting no one actually articulated a claim that there were no mistakes or technical errors at the root of the

⁸ Exhibit P-0481.

⁹ In the end, Dr. Cook, not having received any instructions, signed off in Meditech on the re-test reports for the deceased patients in the same way he had done for living patients.

problem. Dr. McCarthy stated that the meeting was not about errors, though she recalled a discussion about not knowing exactly what the problem was. Dr. Cook recalled that there was a statement about concerns about the system. Ms. Predham expressed the view that it was clear from the discussion that there was no one mistake or technical error that caused this problem. Dr. Singleton was unable to recall the source of the information that there had been no mistakes or technical errors at the root of the problem.

The focus of the discussion became whether Eastern Health should disclose the results of the re-tests to the families of the deceased patients. There was a legal question of which family member would be the proper person to receive such a disclosure, but Mr. Boone addressed it quickly; the issue really was whether to disclose. Dr. McCarthy recounted the experience of oncologists in dealing with families of deceased cancer patients, pointing out that not all family members would want the information. Dr. Singleton and Dr. Bandrauk discussed the concept of a negative right, or the right not to know.

Normally, the person who requests an ethics consult attends the meeting and is, therefore, aware of the discussion. In this case, Dr. Williams was not in attendance. None of those who were in attendance received a copy of Dr. Singleton's report. Consequently, if they disagreed with its content they had no opportunity to say so. Dr. Williams, not having attended the meeting, would not know what the conversation revealed, though he certainly would have known that the underlying premise for the conclusion of the report was not correct. That is, he knew that the statement that there were no mistakes or technical errors at the root of this problem was wrong.

The ethics consult report having been received in June 2006, Eastern Health took no public action respecting the question of disclosure to families of deceased patients until February 2008, after all the deceased had been re-tested. On February 22, 2008, Eastern Health announced through the media that families could obtain the results of the re-tests. As already noted, the decision to re-test the balance of the deceased came in 2007 at the insistence of the provincial government.

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There are some troubling aspects of this ethics consult. I have already referred to the erroneous premise upon which the consensus was based, which in my opinion undermined the validity of the advice given. When one reduces the ER/PR problem to its essential features, there were numerous adverse events (or occurrences) or, some would argue, one very large one. The then existing policies of Eastern Health dictated that there should be disclosure of an adverse event (or an occurrence). The real question concerned the right of families to disclosure in that context. That seemed to have been lost in the process.

The process itself also raises concern. For example, there was no one participating in the consult who might present the perspective of the families of the deceased. In response to questions regarding the perception of bias in the choice of those involved in the consult, Dr. Singleton pointed out that by their very nature ethics consults involve persons with a particular perspective which they wish to prevail. That is a fair point. But in the example of the family and the physician disagreeing about the treatment of a family member, those with opposing views participate. Further, those in attendance included the solicitor for HIROC and the person at Eastern Health who liaised with HIROC. At the time of the ethics consult, a law suit had been commenced against Eastern Health by a ER/PR patient. HIROC had instructed their solicitor to define the action. The participation of HIROC's solicitor and the person from Eastern Health who liaised with him in a consult would create for patients and their families a perception of bias which would well question the integrity of the ethics process and cast doubt upon the advice given.

When attempting to resolve complicated problems, organizations may wish to seek the assistance of a facilitator. Facilitators are skilled at focusing groups on essential points and ensuring that all contribute to the process. Here, Dr. Williams wanted to make a decision about a particular problem. If he wished a facilitator to assist in that process, that is a reasonable approach. An ethics consult, to those outside the organization and, indeed, to those within who do not know the composition of the group, gives the process an aura of an impartial and principled approach

that it should not have in the absence of the participation of representatives of all those involved.

The ethics consult was mentioned in a July 31, 2006, briefing note prepared by Ms. Predham, which was sent to the Department of Health and Community Services:

174 patients are identified as being deceased. In June, an ethics review was conducted regarding notification of the families. The recommendation was that upon conclusion of the ER/PR review, a public statement be made stating that if the next of kin of a deceased patient would like the results, that they contact Eastern Health.¹⁰

Communicating with the Families of the Deceased

In August 2006, Ms. Predham sent to Ms. Hennessey a draft document with information regarding the ER/PR problem. In it she said that of the 176 deceased, 101 had been re-tested and results received and that the remaining [75] will not be re-tested unless the families requested that it be done. Ms. Hennessey, however, did not include the information regarding the 75 not yet having been re-tested in information she provided to Ms Marilyn McCormack, who was preparing a briefing note for Cabinet Secretariat. In preparing the August 18, 2006, briefing note for Cabinet Secretariat, Ms. McCormack relied on the information in the July 31 briefing note of Ms. Predham.

From June 2006, when the ethics consult was completed, to February 2008, when there was finally some official action related to it, there was one employee within Eastern Health who regularly dealt with the families of deceased patients. Ms. Nancy Parsons continued in her role as patient relations officer. In that capacity she took calls from people inquiring about the results of their deceased family member. During 2005, she usually told patients that the living would be re-tested first. She found that families understood and respected that decision. Later, in the absence of a directive from Eastern Health on how to deal with these inquiries, she did the same thing she would have done if a patient were calling. If the result was unchanged (that is, it remained negative), she

¹⁰ Exhibit P-0125, p. 20.

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told the family that. If there was a change in results of the deceased patient, Ms. Parsons believed that it was beyond the scope of her practice to provide that information. This was similar to what had happened when she was calling a patient she believed to be living and was advised that the patient had died. As she was only calling to advise that a patient's result was unchanged, she would ask if the family wished to know the result, and if the response was affirmative, she provided the information.

When there was a call regarding the results for someone who had not yet been re-tested, Ms. Parsons put in a request to Dr. Cook or later Dr. Denic, who would arrange for the re-test to be done. If a request came from the family of a patient whose results had changed, Ms. Parsons was in a quandary. She did not think that she could provide this information. Ms. Parsons asked on a number of occasions what she was to do about the deceased. She was told that Eastern Health had not yet decided how to communicate with families of deceased patients. That decision was not finally made until 2008. Ms. Parsons' inability to respond to certain families resulted in complaints about her giving them the runaround.

There were also family members who had been told that there would be re-testing of their deceased relatives after the results of the living patients had been re-tested and that they would be contacted. Some never received further contact from Eastern Health. Ken McDonald was one of those.

A Family Member's Story: Ken McDonald

Mr. Ken McDonald of Conception Bay South was the spouse of the late Christine McDonald. Ms. McDonald was diagnosed with breast cancer in July 1997. She passed away on January 4, 2000. In addition to her husband, she left a 13-year-old son.

Mr. McDonald learned of the ER/PR issue through the news media in October 2005. He believes he read something in the newspaper concerning inaccurate tests for breast cancer patients during a certain period. A telephone number was given to make inquiries. He called the number and spoke with Ms. Nancy Parsons in October 2005. The NLCHI

database confirms that this contact was made on October 17, 2005. He was told that his wife's hormone receptor status was originally negative and that she would be re-tested. They were doing the living patients first, though. Mr. McDonald understood this. He was in no rush but he asked that his wife's name put on the list for re-test. Ms. Parsons said she would ask that that happen and she would get back to him.

Months went by and Mr. McDonald heard nothing. He called again and was told all the living patients were still not done. He called several more times to ask about the status of the re-testing of his wife's sample, only to be told it still had not been re-tested. He left contact information with Ms. Parsons, including his telephone number and address. He understood that he would be contacted once the re-test results were received.

He finally gave up trying to get information after the Media Technical Briefing by Eastern Health on December 11, 2006. The message he took from this media briefing was that the re-testing was finished. All the living patients had been re-tested and they were not re-testing the deceased.

Mr. MacDonald was not aware of the news release by Eastern Health in February 2008 concerning the results pertaining to the deceased patients. He was still not aware at the time of his interview with Commission Counsel on March 11, 2008, that in fact his wife had been re-tested at Mount Sinai in the fall of 2007. He was provided with contact information for Eastern Health to obtain the details of the re-test. He spoke, on March 13, 2008, with Ms. Sharon Smith, who advised there was some confusion or complexity regarding his wife's test results. Ms. McDonald had had two original ER/PR tests, with conflicting results. Ms. Smith explained this was because "protocols" had changed. Mr. McDonald was not offered any meeting to explain what Ms. Smith felt was a complex matter.

Ms. McDonald's first ER/PR test was done on August 15, 1997, through the biochemical assay method. This yielded a positive result. The second test was done through the IHC method. The results entered on

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her chart on February 18, 1998, were ER negative and PR positive 25%. On February 12, 1998, she was seen by Dr. Wong at the Cancer Centre and he referred to her ER and PR status as positive. The numbers he cited made it clear he was referring to the biochemical assay test. It appears that no one involved in Ms. McDonald's care questioned why the biochemical assay method and the IHC method would produce conflicting results.

Ms. McDonald started treatment with tamoxifen. On June 8, 1998, she was again seen by Dr. Wong. Her disease had progressed. She was switched to Arimidex. By October 1999, Ms. McDonald had brain metastases. Dr. Laing noted in a Progress Note on October 22, 1999, that she had not responded to anti-hormonal therapy.

It appears Ms. McDonald was treated as being hormone receptor positive on the basis of the result of her first test. The second test, which was done using the IHC method and considered negative, is the one that was repeated at Mount Sinai. The results of the re-test were entered on Ms. McDonald's chart on November 30, 2007. The ER had remained negative and the PR, which had originally been reported as 25%, was 0% on re-test. Mr. McDonald had not been offered any explanation as to why the information concerning this re-test had not been communicated to him even though Eastern Health was aware that he had sought to have his wife re-tested.

Mr. McDonald was keenly aware of the ER/PR issue and had sought information about his wife's hormone receptor status. Nonetheless, he missed the announcement by Eastern Health in February 2008 that the re-test results for the deceased were available if families wished to receive them. If Mr. McDonald missed this, it is highly likely that many other families did as well. This was not a sufficient or effective means of communicating with those families.

Mr. McDonald felt that Eastern Health had handled the communication with him poorly. The onus was on him as a family member to look for information, and even when he did so repeatedly,

Eastern Health never took the initiative to respond to him and provide his wife's re-test result.

Eastern Health was reluctant to re-test the deceased patients whose blocks they had put aside initially. Mr. Tom Osborne, as Minister of Health and Community Services, on November 23, 2006, and Mr. Ross Wiseman, as Minister of Health and Community Services, in mid-May 2007 indicated to Eastern Health that this should be done. In his press conference of May 18, 2007, Mr. Tilley, as CEO of Eastern Health, announced that it would be done. He said, "if a systemic review of these tissue samples would help alleviate concerns then I am committed to ensure that this is completed and that patient's families are contacted for follow-up." In a backgrounder to the announcement of the Commission of Inquiry, the Government of Newfoundland and Labrador included the statement, "Eastern Health has committed to re-test results for the 176 patients who are deceased and to ensure that all patients' families are contacted for follow-up." However, as Ms. Patricia Pilgrim aptly put it in her testimony, "we didn't do it for awhile, it didn't happen right away, well then other things happened."¹¹ In the summer and fall of 2007 the slides and blocks of the remaining deceased were gathered together and sent to Mount Sinai. In addition there were newly identified living patients to be re-tested that fall. It was not until 2008 that all of the deceased patients had been re-tested.

The re-testing of the remaining deceased patients was not a rerun of the earlier exercise. For one thing, the relationship with the other regional health authorities was by then different. For example, Western Health did not learn until late October 2007 that the deceased were to be re-tested. As Mr. Robert Thompson explained it, Eastern Health was no longer regarding itself as a coordinating agent for ER/PR testing. So, while Dr. Cook may have originally told Dr. Neil not to send the deceased patients' blocks, when Mr. Tilley publicly made the commitment to re-test the remaining deceased, no one gave that information to Dr. Neil or to anyone else at Western Health until five months after the commitment had been made. Even Dr. Baker, Eastern Health's pathologist in Carbonear, did not learn until September 2007 of

¹¹ Transcript of testimony, Patricia Pilgrim, October 1, 2008, p. 357.

the plan to re-test the balance of the deceased patients and he became aware of it only because of an offhand remark by Mr. Gulliver.

The matter of disclosure to the families of deceased patients became a topic of discussion again after Mr. Tilley's announcement. In July 2007, Ms. Pilgrim and Ms. Jones exchanged emails about the subject. Ms. Pilgrim advised that the Eastern Health Coordinating Committee had discussed ways of notifying families. They concluded that direct notification by mail was preferable, and for any conversions, the paneling process that had been used for living patients would be followed. However, as Ms. Pilgrim put it, they had to go to plan B. The error in the first plan as described by Ms. Pilgrim was that they had not consulted the oncologists and pathologists prior to the development of the plan, and when they did it was clear that the oncologists and pathologists were not prepared to have the same kind of conversations with the families of the deceased that they had with living patients.

By November 2007, the plan for Eastern Health patients was to write letters to the next of kin of deceased patients. The next of kin would be advised that if they wished to obtain the re-test results, they could be obtained at a telephone number provided. If the results were unchanged, the phone number would be that of the Quality Department. If there was a change in results, the phone number would be that of Ms. Sharon Smith, Director of the Cancer Care Program. At that point the plan was still that the next of kin would be put in touch with an external oncologist if further information was required. Eastern Health's attempts to find oncologists from outside the province who might be prepared to do that work were unsuccessful. Another plan had to be developed.

The oncologists at the Cancer Centre were, by that time, indicating that they would assist. They had no hesitation in speaking with families of their own patients where that was requested; their concern related to families of patients whose treating physician was no longer available. Eastern Health had another meeting to try to hammer out a plan. This time they enlisted the aid of Mr. Thompson. By the end of that meeting, the decision was to abandon the idea of direct contact with families of deceased patients. The plan for communication that had been developed

as a result of the ethics consult in 2006 had come full circle, except that now the contact in Eastern Health would be in the Cancer Care Program. On February 22, 2008, the Government did a public release stating that all the deceased had been re-tested. At the same time, Eastern Health announced that next of kin who wished to obtain the results could do so by phoning a number specified. That number was that of Ms. Smith. If the patients came from other regional health authorities, they would be directed to those authorities by Ms. Smith.

Ms. Smith would not provide re-test results for other authorities. She would provide results for Eastern Health's patients, both those who had no change and those who had a change. She would inform the families whether tamoxifen or a similar drug had been prescribed in the case. If further questions were asked, such as what the impact of not having received such treatment might have been, she would offer to put the family in touch with an oncologist. She said that she did not receive many calls requesting results for the deceased, perhaps 12 to 14. The oncologists were co-operative and assisted her when she sought their aid. Ms. Smith, however, became inundated with calls about other matters.

There are two difficulties with the plan finally chosen to communicate with the families of the deceased. First, not all the families heard the announcement. Second, just as not all patients knew whether they had had ER/PR tests, not all next of kin would have had that information and been in a position to determine if the February 2008 announcement was relevant to them.

Chapter Sixteen

**Newfoundland and Labrador Centre
for Health Information (NLCHI)**

Newfoundland and Labrador Centre for Health Information (NLCHI)

The Work of NLCHI

On May 30, 2007, Robert Thompson was appointed Acting Deputy Minister of Health, a position he held until November 6, 2007. At the same time he was appointed chair of the Task Force on Adverse Health Events and Secretary to Cabinet for Health Issues. As Secretary to Cabinet for Health Issues, he was responsible for preparing Government for participation in this Inquiry. The Task Force on Adverse Health Events was created to examine and assess the effectiveness of existing policies for dealing with adverse events, whether they involve one patient or many. The report of the Task Force was presented to Government on December 2, 2008. I have had the benefit of reading the opinions expressed in that report when considering my own recommendations on related issues. Immediately prior to his appointments, Mr. Thompson had since 2003 been the Clerk of the Executive Council, and immediately before that he had been Deputy Minister of Health and Community Services from 2001 to 2003. He was, consequently, very well acquainted with health issues and with most individuals in senior positions within Eastern Health.

Mr. Thompson dates his own loss of confidence in the assertions of Eastern Health that all patients had been contacted to an exchange between himself and Mr. George Tilley early in June 2007. In that exchange, for the first time, Mr. Thompson saw qualifications creeping into Eastern Health's statements about the contacts with patients. On June 11, 2007, he advised the Minister of Health and Community Services and Mr. Brian Crawley of the Premier's Office that on the basis of his review of the briefing notes "we can conclude that we had corporate memory that the 763 living patients could not have all been called in October 2005."¹ I interpret Mr. Thompson to be saying to the Minister and Mr. Crawley that if, within the Department or elsewhere in

¹ Exhibit P-0235.

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Government, a critical analysis had been done of the information received from Eastern Health, they would have known that all living patients who were to be re-tested had not been called in October 2005.

Mr. Thompson then set about trying to determine when contact with patients had been made. First, he sent a couple of Department officials to Eastern Health on the assumption that it would take a few hours, with access to Eastern Health's database, to learn when contact with patients had taken place. The officials quickly reported that the data did not exist in a form from which the information could easily be obtained. There were multiple spreadsheets, they were not all in electronic form, and the definitions were not necessarily the same in all of the spreadsheets. Mr. Thompson decided there was not sufficient expertise within the Department to take on the project. He turned to the Newfoundland and Labrador Centre for Health Information, which "worked on health data and information all the time."

The Project

The Newfoundland and Labrador Centre for Health Information (NLCHI) is an agency of the Crown in right of Newfoundland and Labrador. NLCHI began life in 1997, under the auspices of Healthcare, and continued under Eastern Health until April 27, 2007, when the *Centre for Health Information Act*² came in force. Dr. Donald MacDonald, Director of Research and Evaluation with NLCHI, testified that even in the early days of NLCHI, the roles of Healthcare and Eastern Health vis-à-vis NLCHI were limited to providing administrative services for the agency.

NLCHI began its analysis by focusing on when and how patients were contacted to inform them of the re-testing, and when and how patients were informed of the subsequent test results. Like others before, NLCHI found that the task of gathering and integrating information was difficult. It was being asked to bring together "multiple sources from different parties and reconcile them." The sources were in different regions and different departments, some in electronic format, others handwritten. Some information was contained in emails, notations, and

² SNL 2004, c. C-5.1

even notes. There was information in Toronto. The data was not in “consistent formattings”; NLCHI would have to standardize the formats in order to link and merge and cross reference. Dr. MacDonald explained that “it’s important to realize too back in the early days ... we didn’t realize at the Centre [NLCHI]... how much of this data is actually in hard copy form ... we kind of said ... let’s just go ask for the databases, we’ll get our epidemiologists to link them together, we’ll fill in the gaps, and we’ll go home. It didn’t happen ... I would suggest that perhaps 80% of the data that is incorporated into the database today came from hard copy handwritten spreadsheets, not electronic.”³

As a first step, on July 6, 2007, NLCHI produced a “scoping document” which described three options for the creation of the database. The available options were: (1) to rely on Eastern Health’s database of 939 patients; (2) to seek independent sources to collect the data; or (3) to use a combination of the first two methods. The disadvantage of the first was that NLCHI would not be able to say whether it had identified all the cases. Using the second option, NLCHI might be able to overcome that disadvantage, but it would be very lengthy and costly. The third option, the one chosen, involved creating a database of all ER/PR tests done from May 1997 to August 2005. However, it was quickly determined that this was also going to be a very lengthy process. Consequently, Mr. Thompson directed NLCHI to concentrate on the cases where there had been a negative result on the original test. In other words, NLCHI was examining only those cases that were within the criteria originally set by Eastern Health for the re-test.

As to what material NLCHI would use to gather the data, it was agreed that they would use only written information, which was assumed to be accurate. It was not part of NLCHI’s assignment to do any audit of the data or determine its reliability. (Later Eastern Health performed its own audit to ensure that contacts with patients had been made, and that information confirming patient contact was incorporated into the data compiled by NLCHI.) NLCHI obtained the pathology

³ Transcript of testimony, Dr. Donald MacDonald, October 23, 2008, pp. 49-50.

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reports for all negative⁴ ER/PR tests done for the time frame under review from all the regional health authorities except Eastern Health. For Eastern Health data, NLCHI relied on spreadsheets provided by Eastern Health; the information in the spreadsheets, in the majority of the cases, was supported by data located in Eastern Health's Meditech system.

For NLCHI, a critical piece of data was the Medical Care Plan (MCP) number. It was the unique identifier that would enable NLCHI to distinguish between patients with the same name and identify patients who had changed their names. Mount Sinai did not use the MCP number in recording their data because they did not need to do so. Eastern Health had provided NLCHI with two main sources of information: the "August 1st file,"⁵ which was in electronic format, and Mr. Terry Gulliver's spreadsheets, which were handwritten. It was only Mr. Gulliver's handwritten spreadsheets that contained MCP numbers. A great deal of effort went into verification of MCP numbers for patients and dealing with something called a "pseudo MCP number," which the system sometimes generates on a temporary basis. Dr. Reza Alaghebandan of NLCHI explained the pseudo MCP number as follows:

... I can recall sometimes we had an NL resident, Newfoundland and Labrador resident who must have had a valid MCP, yet the patient had what we call pseudo MCP, let me give you a scenario here, a patient was sent from Western Memorial to St. John's for ER/PR retesting. For some reason, they forgot to mention the MCP for that patient, so once we received that patient in here, in St. John's, the Meditech system automatically generates a pseudo MCP number for that patient, so that's one of the challenges that we had, so we captured that pseudo MCP from Meditech, yet we had to go back to MCP registry to find the proper MCP number for that patient so we'd be able to do the rest of the cross-referencing and linkages down the road. That was one of the challenges that we had.⁶

One of the objectives of the NLCHI work was to determine when blocks were sent to Mount Sinai, when they were received by that

⁴ NLCHI did not specify how "negative" was defined for this purpose. That was left to the regional health authorities.

⁵ The file was so named because NLCHI received it from Eastern Health on August 1, 2007.

⁶ Transcript of testimony, Dr. Reza Alaghebandan, October 23, 2008, pp. 89-90.

institution, when the results were returned to Eastern Health, and when and how the patients were told of this information. One might think that this, at least, would be a relatively easy task in an age of technology. Not so. Mount Sinai recorded when the order for the test was entered on their system, not when the blocks were received. Even the date the sample was sent from Eastern Health, as recorded in Meditech, was sometimes incomplete. Sometimes only the year or the year and month were recorded. Dr. MacDonald was quick to point out that this latter point was a data management issue, not a technology issue. NLCHI was never able to obtain copies of all of the emails from Mount Sinai enclosing the Excel spreadsheets⁷ of re-test results to determine when results were returned, and, in any event, some of those were returned in hard copies. Further, the consult cases complicated things. NLCHI had initially assumed that all retrospective results were recorded on the spreadsheets, but those consults which were part of the retrospective were not reported in that way. They were reported individually. The fax cover sheets accompanying the consult reports were not kept. In short, the date the results were received from Mount Sinai was available for some of the re-tests, but not for all. In the end, NLCHI recorded the date the re-test results were entered into Meditech by Dr. Donald Cook or one of the other pathologists. Dr. MacDonald and Dr. Reza Alaghehbandan recognized that that date might be some days or weeks after the results were received but it was chosen because it was available for all of the re-tests. Similarly, for the receipt of blocks at Mount Sinai, the date used was the date the block was entered into the Mount Sinai system, not the date it actually arrived in Toronto. Any assessment of turnaround time at Mount Sinai would, at best, be an approximation that would likely be longer than the actual time.

When NLCHI entered into the project, the concern being addressed was whether all patients had been contacted. At that point no one was asking whether all patients had been identified for re-testing. NLCHI raised the question in late July 2007. It was August or September 2007 before Mr. Thompson was told that there had indeed been patients missed in 2005. Dr. MacDonald did not initially see direct contacting of

⁷ Results of the retrospective were generally reported by Mount Sinai on Excel spreadsheets emailed to Dr. Cook.

regional health authorities as part of NLCHI's role. However, by October 2007, NLCHI's role had expanded, and it regularly contacted the regional health authorities when the data led NLCHI to question whether a patient had been contacted. As this was seen as a patient care issue, Mr. Thompson, in his capacity as Deputy Minister of Health, contacted the regional health authorities, asking that they take action to deal with the matter of unidentified patients. Mr. Thompson too became involved at a level he had not anticipated. He said:

We thought that the database that we were engaging in back in June/July of '07 was one of, you know, a limited exercise of integrating existing data into one spread sheet and then we have a picture emerge before us of something not too complex, but as each month passed, we're, of course, being impressed by its complexity. But on top of that we're being drawn into, almost at the operational level of the management of cases and that wasn't the role of the task force or the role of the Office of Secretary to Cabinet. But whenever--we felt we had a duty or obligation, that whenever we identified something of an operational nature that we think Eastern Health should do, well, we would try to identify that. So, for example, from the outset, we had told NLCHI that whenever and if you ever and whenever you identify a case that should have been retested, but wasn't, make sure that Eastern Health is alerted to that so they can get the resting [re-testing] process under way right away.⁸

One example of the type of discovery made by NLCHI was that a number of deceased patients of Western Health had not been re-tested. This was because in 2005 Western Health had understood that the deceased were not being re-tested. Another arose when NLCHI was seeking pathology reports from Carbonear. On reviewing the pathology reports he had collected to provide to NLCHI, Dr. Gary Baker discovered that patients who should have been considered negative for the purpose of the re-test had been improperly identified as positive and therefore not re-tested.

Mr. Thompson's group at the Task Force, with the assistance of NLCHI, from January to March 2008 produced a number of statistical tables based on the information gathered by NLCHI. In speaking to the accuracy of the data, in his testimony of May 9, 2008, Mr. Thompson opined that there was a high level of reliability in respect of the clerical

⁸ Transcript of testimony, Robert Thompson, May 9, 2008, pp. 257-258.

data, the tests, and the re-test results. However, he added that there remained a small possibility that there were individuals who had had an original test, but who had not been identified in any searches conducted to that point. Mr. Thompson first gave testimony on May 7-9, 2008. He concluded his testimony on October 24, 2008, at which time he confirmed that between May 2008 and late August 2008, another 10 people had either identified themselves as persons who should have been re-tested, been so identified by a relative, or been discovered by a regional health authority. By October 2008, the Minister had directed that a final search strategy be conducted by each of the regional health authorities. That work has not yet been entirely completed.

Both Dr. MacDonald and Dr. Alaghebandan stressed the limited nature of the assignment NLCHI had received, directed as it was to whether a discrete group of people had been told about the re-test and the results. Dr. MacDonald emphasized that this was a database management project, not a research project, and NLCHI was never asked nor intended to approach its involvement in the ER/PR matter as an epidemiological research study. As he put it, this was just a “straightforward math exercise.”

However, in doing its work NLCHI collected other data. It then began to question whether other information could be gleaned from the project. However, Dr. Alaghebandan warned of the dangers of coming to incorrect conclusions from the raw data without other relevant information.

Dr. MacDonald advised the Commission that various tables were prepared to try to determine if the ER/PR problem was systemic, or whether it was focused on a particular time period or geographic area. Until late October 2008, when Dr. MacDonald gave evidence, no definitive answers had been found, though he did point out that in any event the sample size from some areas of the province might be so small as to preclude any conclusions being made on such a basis. Eastern Health had asked NLCHI to look at temporal variations in results, but that work had not then been completed.

As to the omission from re-testing of the many hundreds of ER positive cases, Dr. MacDonald agreed that that was a limitation to the database. This aspect of the matter is discussed in the Chapter entitled “DCIS and Retro-converters.”

Information that can be Gleaned from NLCHI’s Database

For quite some time, Eastern Health said that 939 patients had been re-tested.⁹ NLCHI was never able to determine how the figure of 939 was calculated, perhaps because each time the spreadsheets were updated by Eastern Health the existing ones were overwritten. NLCHI concluded that the total number of patients re-tested was 1013 as of March 11, 2008. This figure included 18 ER patients identified by NLCHI as positive. There were 1101 re-tests performed for the 995 ER negative patients. NLCHI estimated that five to ten percent of all re-tests were done on a paraffin block that was not the one used for the original test.

NLCHI’s data also demonstrates that the figures used by Eastern Health were not necessarily updated as time went on. The most obvious example is the number of deceased, which remained at 176 from the first identification of that number in an August 11, 2006, communication to the Department of Health and Community Services. NLCHI noted that by November 23, 2006, 295 of the 1013 patients could have been identified as deceased had Eastern Health used the provincial mortality database. In March 2008 NLCHI confirmed that the number of deceased ER/PR patients had by December 2007 risen to 326.

Eastern Health originally intended that the ER/PR tests sent to Mount Sinai be limited to those involving primary breast carcinoma. NLCHI reports that at Eastern Health 4-5% of all ER/PR tests would have been for purposes other than primary breast carcinomas. The percentage of ER/PR tests done for non-primary breast carcinomas by the other regional health authorities was not available to NLCHI.

⁹ That figure appears in the material for the media technical briefing in December 2006 and in Ms. Predham’s affidavit of February 9, 2007, filed in the class action suit against Eastern Health.

Information Which Must be Said to be Suspect

One concern about the data stems from uncertainty about the percentage of positivity used by oncologists to determine if an anti-hormonal drug was to be offered, particularly during the years 2000, 2001, and 2002. There were, of course, oncologists who always used 10% positivity as a prerequisite for consideration for treatment with tamoxifen or an aromatase inhibitor. Dr. Joy McCarthy, who arrived at Healthcare in mid-2001, was one of those oncologists.

As was noted in the March 11, 2008, report provided by Mr. Thompson, there was also uncertainty over whether all pathologists were using the same cut-off points. In the most recent version of the NLCHI database, received by the Commission in October 2008, just under half of the original negative ER reports were recorded as “Neg” or “N,” with no percentage of positivity used. For those cases, it is not possible to say what percentage was considered by the pathologist to be required for the designation positive. Nor is it possible to say what any one oncologist might have interpreted that phrase to mean. The assumption made at Eastern Health, and therefore by NLCHI, was that before 2001 a negative result would have been equal to or less than 30%, and after that it was equal to or less than 10%.

Further, if one is trying to do an assessment of percentage of nuclear staining, the difference between 25% and 30% staining is unlikely to be significant in the assessment of percentage by a pathologist, though prior to 2001 it might have been critical for a determination of treatment. A change from 35% to 90% might not be considered to be significant for treatment, but would certainly be significant for any analysis of the validity of the testing.

When I say that this information must be said to be suspect, I do not imply that NLCHI failed to do something it was asked to do. I am merely pointing out the danger of inferring, from data collected for a limited purpose, conclusions which the data does not and was never

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intended to support. The present data is not reliable enough to allow for definitive, science-based statements about percentages of change other than the obvious one as to the percentage of persons re-tested who went from clinically negative to clinically positive. Even that statement is based on the assumption that when pathologists were reporting results as simply negative or positive, oncologists understood correctly what the pathologists were saying.

Conclusion

It is readily apparent that the Eastern Health team examining this problem from the early stages should have included an epidemiologist and persons skilled in the collection and organization of data. NLCHI had a close relationship with both Healthcare and Eastern Health. It is difficult to understand why NLCHI was not consulted when Eastern Health began to collect and organize the data in 2005.

The efforts of NLCHI to bring order to the chaotic data led to the identification of a number of persons for re-testing who likely would not otherwise have been identified. That was a very valuable collateral benefit of NLCHI's work.

Mr. Thompson anticipated that positivity rates might help the Commission to determine if the problem could have been detected earlier. Mr. Thompson stated that absent the advice of experts, his group was not in a position to make decisions about the calculation of positivity rates. For example, should positivity rates be calculated on the basis of ER alone, or ER and PR? The same has to be said about rates of change. Mr. Thompson acknowledged that his Task Force group had talked to "a fair number of people" about those questions as they related to calculation of positivity rates, but no conclusion had been reached. He acknowledged that opinion on the subject could vary from epidemiologist to epidemiologist. Mr. Thompson's group never did find any epidemiologist who was prepared to comment upon the issue of making such a choice at all.

Some will be disappointed that I have not determined the rate of positivity based on the re-tests. That could only be done if I were to

assume that all those who were not re-tested were in fact ER positive. Dr. Alaghehbandan testified that in his view one would never include in a calculation of false positive results any originally positive results that had not been re-tested and reported by a gold standard centre. Logically, the same must be said of any calculation respecting positivity rates. In addition, in my view the really important question related to positivity rates is based on what Eastern Health believed those figures to be at the time, not on what they actually were.

Would tracking of the positivity rates have made a difference had it been done? Assuming that what was viewed as being the appropriate rate of positivity was not as wide as the 50 to 85% suggested in the early stages of the ER/PR problem, I conclude that it would have. That does not mean I can conclude that any particular patient's results would have been recognized as incorrect. I am merely concluding that had the tracking of the metrics been properly undertaken, it should have caused further investigation to take place.

Proper tracking would have caused Eastern Health to examine the method of reporting and, at a minimum, clarify what positive, weak positive, and negative meant within the laboratory and to the oncologists. That is, proper data collection would have helped clarify what was going on at the time.

If one accepts that the tables produced by Mr. Gulliver in 2005 reflect what Eastern Health would have produced during the relevant years, those results would have indicated there was a problem. The variation in annual positivity rates in those figures was quite large. Exhibit P-0530 provided rates for the years commencing 1999. The lowest year was 1998, when the ER positivity rate province-wide was 26.4%, and the hormone receptor (ER/PR) positivity rate province-wide was 41.3%.¹⁰ Unfortunately, when Eastern Health was using positivity rates to reassure others, including the Government, that their test results were likely within "the margin of error," they averaged the total number of years, when they should have been examining the percentages on a quarterly, or at most a yearly basis. When Eastern Health was suggesting

¹⁰ Exhibit P-3505, p. 11

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that 73 or 75% was to be anticipated for its population, it knew that in 2000 the rate was 62%, and in 2002, just before Dr. Gershon Ejeckam's intervention, the rate was 68%. In 2003, the year of Dr. Ejeckam's intervention, the rate rose to 83%. It is not possible to say whether the difference is attributable to Dr. Ejeckam's adjustments in the laboratory, to his memo to pathologists in the spring of 2003, or to some other factor(s).

If someone had also been tracking clinically significant changes for individual patients, following isolated re-testing of their surgical specimens, as we know that there were at least four in this time frame, the combination of all of this data would likely have caused an extensive investigation at the time.

However, it is important to remember that Dr. Brendan Mullen cautioned:

What I've tried to get across, the concept that statistics are nice, but it's the individual case that we live and die on. If my aggregate statistics are fine, but I misdiagnosed or the ER/PR [is] misinterpreted or on the individual case, that's 100 percent error rate for that patient.¹¹

¹¹ Transcript of testimony, Dr. Brendan Mullen, June 27, 2008, p. 324.

Chapter Seventeen

Governance and Accountability

Governance and Accountability

Governance

Mr. Abbott, who had been chair of the Board of Trustees of Healthcare, and Ms. Dawe, who is chair of the Board of Trustees of Eastern Health, each testified about the governance models chosen by their respective boards. Ms. Dawe explained that Eastern Health's Board had chosen a modified policy governance model; Mr. Abbott described Healthcare as having had a hybrid model, though he believed it was closer to the policy governance model than to the administrative model.

The regional health authorities were created by Order¹ under the authority of the *Hospitals Act*.² The *Regional Health Authorities Act*, SNL 2006, C. R-7.1, under which Eastern Health and the other regional health authorities currently operate, was not proclaimed until April 1, 2008. Consequently, when the problem arose and when the major decisions regarding the management of the ER/PR problem were being made, the boards were operating under the *Hospitals Act*. The *Hospitals Act* provides that a hospital board is a corporation (s. 4). A board's purpose is to manage and control the operation of the hospital or hospitals identified in the order creating each board. Sections 16 and 17 of the *Hospitals Act* specified the authority of the board to hire staff and outlined its powers and duties. Ms. Dawe stated in testimony that she had been advised by Mr. Ottenheimer, the Minister of Health and Community Services, that the board should govern itself as if the new legislation were in force. In their submission to the Commission, the Board of Trustees of Eastern Health stated that it "was able to draw upon the additional guidance provided by the *Regional Health Authorities Act*...and the *Transparency and Accountability Act*. which has helped remedy the problem of poor role definition posed by the former *Hospitals Act*." These and other sources led the board to conclude that a modified

¹ The Regional Integrated Health Authorities Order, Newfoundland and Labrador Regulation 18/05.

² RSNL1990, c.H-9.

policy governance model should be adopted. In the conclusion to its submission to this Commission, the board stated:

... the Board of Trustees of Eastern Health have developed a modified policy governance model and have taken great strides to adopt that model for the organization. In order to do this, the Board of Trustees relied upon a variety of sources, and has developed a model suited to the specific organizational needs of Eastern Health. Given the size of the organization and the extremely complex nature of health-care services, it is reasonable and prudent of the Board of Trustees to rely upon the advice and guidance of the professionals employed by Eastern Health with regards to the day-to-day management of the organization, all the while focusing its efforts on strategic planning, policy making and accountability to the stakeholders.

The *Hospitals Act* required the board to manage and control the operation of the hospitals under its jurisdiction. The Minister's advice could not change that. A board cannot limit its responsibilities, whether imposed by the *Hospitals Act* or otherwise, by the choice of governance model. A board may choose to delegate certain responsibilities. However, that does not make it any less accountable for them. Further, the size of the corporation does not alter the basic principle of accountability. If that were so, the larger the corporation, the less accountability the board of directors would have.

In its submission to the Commission, the Board of Trustees quotes from "Board of Governance - When does it become Director's Negligence," by Donald J. Bourgeois. In that article the author reminds the reader of the two aspects of the role of the board: governance and stewardship. The latter is "the responsibility of the board of directors of an organization and involves the active oversight by the board of the organization's governance." I would expect that any good governance model, whatever its name or philosophy, would include accountability, transparency, and strategic planning.

The choice of a policy governance model highlights the board's role as the developer of policy. It does not tell the executive how to achieve the ends it has identified, though it may tell the CEO that certain means are to be avoided. Many of the policies of the Board of Trustees of Eastern Health are framed in the negative. This was a deliberate choice

by the Board of Trustees, which presents in its policies the ends to be achieved by the organization and allows the CEO to use any reasonable interpretation of the policies. Sometimes a policy may set limits on the means to be used to achieve the ends, but otherwise the means are at the discretion of the CEO. Ms. Dawe's view was that the positive approach would be much more constraining to a CEO and, from the perspective of the board, would result in a less inclusive policy.

The board policy on *Communications & Support to the Board*, No. EL-2³, approved May 24, 2006, provides that the chief executive officer shall not permit the board to be uninformed or unsupported in its work. The Policy provides specific examples. For example, the CEO shall not "let the Board be unaware of relevant trends" or "anticipated adverse media coverage" Policy No. BS-4 underlines that the Board works only through the CEO. It states: "The Board will view the Chief Executive Officer's performance as identical to organizational performance, so that organizational accomplishment of Board stated Ends and avoidance of Board proscribed means will be viewed as successful Chief Executive Officer performance unless other criteria have been specifically established."

None of the policies of Eastern Health had been developed in the summer of 2005 when the ER/PR problem broke. Mr. Tilley would have been expected to operate in the way that he had operated under Healthcare until development of some new Eastern Health policies.

Healthcare and Eastern Health's organizational structure both had the CEO reporting to a Board of Trustees. Though Mr. Tilley had planned to change the role of the CEO to concentrate more on policy development, during the time relevant to this Inquiry the responsibilities of the CEO were generally the same under both organizations. The responsibilities of those in other executive positions within Healthcare and Eastern Health changed from time to time as exigencies or organizational requirements demanded. For the purpose of this Inquiry, it should be noted that while the Vice-President Medical was responsible for the laboratory medicine program throughout the whole time, the

³ Exhibit P-0052, pp.21-22

Quality Department reported to different positions over the relevant period.

Accountability

In the course of the Inquiry, issues of transparency and accountability, legal and ethical accountability, accountability to the stakeholders, professional accountability, and political accountability were raised. While the underlying principle of accountability is the same, what the obligation demands may vary with the nature of the duty and responsibilities conferred or delegated. In some contexts accountability may involve discipline, but that is not a necessary element.

In the *Inquiry into Pediatric Forensic Pathology in Ontario*,⁴ Justice Goudge uses a simple but helpful definition of accountability: “the obligation to answer for a responsibility conferred. When called on to account, a party on whom responsibility has been conferred must explain and justify – against criteria of some kind – his or her decisions or actions.” Justice Goudge also addresses the other side of the coin: oversight. He states: “Once responsibility is conferred, oversight seeks to ensure that the responsibility is properly fulfilled. The overseer must ensure that those who hold the responsibility in fact discharge it and are held accountable for their actions and decisions.”

Generally, the owners of a corporation may confer responsibilities on the corporation or, in the case of corporations created by statute, the responsibilities are conferred by legislation. Within the corporate structure, the conferring of responsibility comes from the top down, from the board to the CEO to the various Vice-Presidents, etc. Each individual becomes accountable for his or her area of responsibility. A person who confers a responsibility generally oversees those upon whom the responsibility is conferred. As noted above, regional health authorities are corporations and, therefore, must be concerned with corporate accountability.

⁴ Goudge, Stephen T. Hon. *Inquiry into Pediatric Forensic Pathology in Ontario*, Toronto: QP, 2008.

In its submission to the Commission, the Board of Trustees of Eastern Health further refers to “Board Governance – When Does it Become Director’s Negligence,” to make the point that one cannot actually expect a Board of Trustees to manage a large corporation:

There are practical limits to the abilities of directors to manage the affairs of large organizations with many employees. It is physically impossible for these directors to make all of the decisions that are required to be made on a day-to-day basis. Arguably, these directors could be negligent if they attempted to do so because decisions would not be made by the person most competent to do so, the decisions would not be made in a timely manner and the directors would be wasting the skills and talents of its employees.

I entirely agree that a Board of Trustees of a regional health authority should not become involved with the day-to-day operation or management of the organization. It does not follow, however, that directors’ responsibilities are limited to the setting of policy. If that was the intent, there would have been no requirement for the legislative structure for regional health authorities which exists at present or for their predecessor corporations. The directors, or in this case trustees, thus are ultimately responsible and accountable for the management of the corporation.

Fiscal responsibility has always been seen as critical for a corporation and commonly one sees reference to the responsibilities of boards of directors, even where the day-to-day affairs of the corporation, such as establishing a budget and monitoring and controlling expenditures, are delegated to management. Audit or finance committees of boards of directors are quite common. Indeed, Ms. Dawe noted that one of the commitments of the Board of Trustees of Eastern Health has been to maintain a balanced budget. She said that there is a Finance Committee and monthly reports are sent to the entire board. She added:

We very carefully monitor our financial stability. To ensure stability, we had to make sure that we were on, you know, for obvious reasons, we do not have variances from the plan. So if there was something that was brought to our attention through the monitoring process and through the Finance Committee, then we would intervene and provide that kind of direction.⁵

⁵ Transcript of testimony, Ms. Joan Dawe, March 26, 2008, p. 52.

A regional health authority does not produce widgets; the marketplace is not going to determine if the organization survives. Its clients have no choice but to use its services; they cannot stop going to the hospital because the services received on the last visit were unsatisfactory. In my opinion, this reality means that for a regional health authority, where the marketplace is not in a position to ensure that the product meets acceptable standards, particular emphasis must be placed on quality of the service provided. That means ensuring that there are quality control and quality assurance procedures operating within the organization. By establishing a Quality Committee at the board level, the Board of Trustees of Eastern Health has already recognized that quality is important. Quality has to be given importance equal to that of the budget.

It is not sufficient for a committee or a board merely to accept reports of management without examination and analysis. At a minimum, the board must exercise due diligence to ensure that the owners of the corporation (ultimately the people of Newfoundland and Labrador) are receiving value for the funds which the board carefully monitors. The reports to the Board of Trustees of Eastern Health regarding the ER/PR problem were obviously deficient. They minimized the problem. Ms. Dawe's understanding of the problem demonstrates that point. While the management is responsible and accountable for the quality of the reports provided to the board, the board allowed the management of Eastern Health to provide less than adequate information relating to the ER/PR problem and for that they are accountable.

Healthcare

For any corporation, including those providing a service, certain basic organizational imperatives exist. To enable accountability and oversight to function properly there must exist within the corporation:

1. Standards for the performance of the work;
2. A review and, where proper, an updating of those standards on a regular basis;

3. Standards to ensure that those performing the work have the ability and knowledge to do so;
4. Documentation of actions taken;
5. Supervision and quality control;
6. Clear roles and responsibilities for all involved.

From profession to profession or industry to industry, the language used to express these basic priorities may be different. One of the common statements about ER/PR testing has been that there are no national standards. That does not mean that within a laboratory there are no values against which the work must be measured. Procedures and protocols fulfill this function. A semantic discussion about the difference between a standard and a protocol does not invalidate the principles set out above. Even in the absence of national standards, ER/PR testing must be done consistently, in accordance with protocols, though certain aspects of the methodology may and should vary from laboratory to laboratory.

As the evidence placed before the Commission demonstrated, there were serious deficiencies in Healthcare's application of each of these organizational imperatives.

Standards for the performance of the work

For performance of ER/PR testing, Eastern Health/Healthcare could refer only to excerpts from the DAKO Autostainer manual and a summary of procedures that had been prepared for technologists when the procedure was a manual one. When the Ventana Benchmark was introduced, its manual replaced the one for the DAKO Autostainer. This was completely inadequate, as Ms. Predham acknowledged in her evidence, though Mr. Gulliver was not prepared to concede there were deficiencies. In my opinion, there were no proper standards for the performance of ER/PR testing.

A review and, where proper, an updating of those standards on a regular basis

Compounding the lack of standards for performance was the absence of a program for the review and update of the standards for

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ER/PR testing. There might have been, at Healthcare, in respect of fixation and tissue processing, certain standards, but there was never a systematic review and update of them. In other health care corporations outside St. John's where fixation and tissue processing was performed, there were manuals but these were not regularly reviewed and updated.

Standards to ensure that those performing the work have the ability and knowledge to do so

As to the performance of the work of ER/PR testing, generally those involved as technologists had the training required to become a registered technologist or medical laboratory technologist. However, ER/PR testing, which is part of immunohistochemical testing, requires additional training generally done in-house. Healthcare's training of technologists did not provide those doing the work with the knowledge and skill necessary for ER/PR testing and the performance of all the other tasks expected of IHC technologists, such as troubleshooting. Pathologists working in the laboratories were vetted by the appropriate committees within the organizations. When, in 1998 the decision was made to have ER/PR slides read by pathologists in the various hospitals, rather than by one pathologist in St. John's, no one ensured that these pathologists, many of whom had no experience in reading ER/PR slides, had the knowledge to do so. Once technologists and pathologists are properly trained, their knowledge must not remain static. There are new methods and new tests being developed on a constant basis. There must be methods of ensuring that the skills of those performing these tests are kept current. While there were sporadic opportunities for continuing education at Healthcare during the relevant time period, they were certainly not adequate.

Documentation of actions taken

The documentation of actions taken was erratic. It fell far below the standard required of a laboratory. This deficiency was made very clear by the ER/PR problem.

Supervision and Quality Control

Quality control and quality assurance were deficient. Technologists assumed there was a system of review by pathologists, which did not exist. There were minimal quality control procedures. There was no external proficiency testing.

Clear role and responsibilities for all involved

Job descriptions for those involved were dated, non-existent, or vague. The lines of accountability and oversight were unclear.

Conclusion

These deficiencies were major factors in the creation of and failure to detect the problems in ER/PR testing. To use Mr. Tilley's phrase, it was a "system problem." The failures did not stop at the laboratory door. The fact that this problem existed for such a long time without discovery demonstrates not only deficiencies within the laboratory but also the failure of Healthcare's management system.

Eastern Health

I turn now to the actions taken after the discovery of the ER/PR problem. In the immediate aftermath of the discovery of the problem, in my opinion Eastern Health took the proper steps. With the assistance of Dr. Carter, efforts were started to determine the nature and size of the problem. Dr. Laing and Dr. McCarthy were trying to identify patients who had the same diagnosis and hormone receptor status as Ms. Deane and those whose diagnosis and hormone receptor status might suggest a similar result. Up to the end of July 2005, patients whose results changed on re-test were told of the change and treated accordingly. When the investigation proceeded to the point where it was clear that a problem existed and that it was a significant one, Dr. Williams told Mr. Tilley who in turn advised the chair of the Board of Trustees. The Minister was advised. It was not unreasonable, at that early stage to have no public communications. Thereafter, however, the issue was badly managed by Eastern Health.

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The overarching issue regarding the management of the ER/PR problem is the absence of a crisis management plan. The failure to document actions taken and the absence of clear roles and responsibilities for those involved, the confusion arising from lack of dedicated resources and the lack of timely response all stem from this.

When it became clear that the problem was a large-scale one, it was agreed that Dr. Carter would undertake a comprehensive review involving all ER/PR tests done to the point where Eastern Health stopped using the DAKO Autostainer, and include re-tests, a review of the original slides, and quality assurance. In short, an investigation to determine the cause of the problem commenced.

After August 2, 2005, when Dr. Carter resigned from the in-house investigation of the ER/PR problem, Eastern Health abandoned any real science-based investigation of the cause of the problem. It became a patient identification project. The re-testing at Mount Sinai was limited to ER negative cases. There was no intention of re-testing any positive ER cases. The only activities after August 2, 2005, by Eastern Health which can be said to contribute to any investigation of the problem are the reports of Dr. Banerjee and Ms. Wegrynowski.⁶ Both are valuable contributions but cannot be said to provide a complete investigation. Dr. Banerjee, on the basis of a limited number of slides⁷, made observations about the quality of the slides and the work of pathologists. He was troubleshooting. Ms. Wegrynowski was able to identify serious deficiencies in the laboratory practice. That too was helpful in assessing the problem. It was even more valuable for the efforts to address the problem. I conclude that after August 2, 2005 the complete focus of the effort was on identifying patients whose treatment might be changed had they had the correct ER/PR results. While I agree that a patient care perspective should be taken, in the management of a problem such as this one, an effort to assess the cause of the problem with a view to preventing recurrence should not be ignored.

⁶ It was not until the Commission requested that Dr. Mullen review a number of original ER/PR slides that that was done.

⁷ Dr. Banerjee said that he examined approximately 20 ER/PR slides and slides from "30 odd" other types of cases.

Eastern Health's work of identifying patients was hampered by poor information management under Healthcare. Within Eastern Health, there was inadequate documentation of the work of the Group or the Core Group, and no record-keeping existed, in spite of the large number of emails which this issue seemed to generate. This caused many misunderstandings. A number of witnesses referred to the problem as having been managed "off the corner of the desk." I take that to mean that all those involved were continuing to carry their regular duties and the ER/PR problem was something additional. The problem was too big and complex to be properly managed in that way. There were external resources, such as NLCHI, which were not tapped by Eastern Health while the problem was being dealt with. Decisions were put off until matters were urgent. For example, the Group waited until the re-test results were coming back before starting to think about how to communicate with patients. On the management of the issue, some of the Group were asked to carry a larger share of the burden than reasonable. Ms. Predham and Ms. Bonnell both demonstrated, on occasion, the strain of the workload. Proper management of a crisis includes ensuring that sufficient people and resources are devoted to the task.

Transparency and Accountability

Regional health authorities, as agents of the Crown⁸, must also comply with the *Transparency and Accountability Act*. While the Act does not define accountability, the *Transparency and Accountability Guidebook* says:

Accountability clearly establishes the right of citizens to know what government and its entities intend to achieve on their behalf and how well they have met these intentions" (CCAF 1999). In the most general terms, accountability means the ownership of conferred responsibilities, combined with an obligation to report to a higher authority on the discharge of these responsibilities and on the results obtained. To be accountable, an organization must be clear about its goals and objectives, the full costs of related strategies,

⁸ Section 6(4) of the *Regional Health Authorities Act*, SNL 2006, c. R-7.1

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and report on its actual results. It must also report and explain any differences between expected and actual results.⁹

It is to this legislation that Ms. Dawe attributed the requirement for Eastern Health to develop a strategic plan and to report publicly.

Minister of Health and Community Services

Political accountability is also at play in the ER/PR problem. The Minister of Health and Community Services is accountable to the House of Assembly with respect to regional health authorities. The relationship between the Minister and the regional health authorities (and the reporting lines) is not always clearly understood. The Minister appoints Board of Trustee members and approves budgets of the regional health authorities, as was the case for the predecessor corporations. The evidence regarding the relationship between the Minister and the regional health authorities, and the role of the Department of Health and Community Services leads me to conclude that historically:

1. Usually the regional health authorities are left to decide matters within their own organizations and neither a Minister nor the Department interferes in operational matters.
2. If a Minister wishes to have a particular course of action taken, that is generally put in the form of a request.
3. Requests are often, but not always acted upon.
4. There is a point at which a request becomes an order which a Minister expects to be followed.¹⁰
5. A Minister expects that the regional health authority will provide him or her with the information required to enable the Minister to fulfill the responsibility to account to the legislature.

⁹ *Achieving Excellence 2006: A Guidebook for the Improved Accountability of Government Entities* Transparency and Accountability Office, Government of Newfoundland and Labrador

¹⁰ The *Regional Health Authorities Act*, which came into force on April 1, 2008, specifically addresses the Ministers authority to give a regional health authority directions and the obligation of the regional health authority to follow those directions. Prior to the enactment of that legislation there was some question about the legal position of each when the Minister made a "request."

6. The Department is heavily involved in budgetary matters as the source of funding for the regional health authorities is the Government of Newfoundland and Labrador.
7. This includes an acceptance by the regional health authorities, albeit a reluctant one, of the oversight activities of the Department related to budget issues.

The Government of Newfoundland and Labrador has submitted to the Commission the following as an approach to be used to ensure that the Minister is in a position to fulfill his or her responsibilities:

Although Ministers and Departmental officials recognize that subordinate agencies are accountable to the legislature through the Minister, there are no written procedures or expectations on how to fulfill this accountability during a serious adverse event. Thus, throughout the ER/PR Issue, formal guidance for Ministers on this type of issue did not exist. In consequence, the following expectations are advanced. Due diligence by the Minister and Departmental officials requires the collection and examination of information. The regional health authorities briefing for the Minister on a serious occurrence or adverse event should address the following points (in one or more briefings as the information becomes available):

- 1) Action being taken to avoid further potential harm to patients;
- 2) Action being taken to provide diagnosis and treatment for patients who may have been harmed;
- 3) Action being taken to determine the causes of the problem;
- 4) Explanation of the causes of the problem to the Department;
- 5) Explanation of how the problem is being fixed based on the identified causes; and
- 6) Action being taken to disclose the problem to patients and, if necessary, inform the public.

It is conceded by the Government that a Minister must exercise due diligence in evaluating such information. Its submission adds:

If the information provided by the regional health authorities satisfactorily addresses these points, the Minister has discharged the accountability function.

If the answers are not satisfactory, the Minister can ask for additional explanations, ask for alternative courses of action to be considered, or issue a directive for different action under the authority of the *Regional Health Authorities Act*. The directive power under the *Act* was not created with this type of use in mind; nonetheless it does exist if necessary. If ever used in this

context, of course, it would be a serious expression of lack of confidence, and thus a sign of a deeper problem.

The current legislative structure clearly establishes a relationship between the regional health authorities and the Minister and it is, in my view, the Minister who must exercise the oversight role. In the context of the ER/PR problem, it was the failure of the Department on behalf of the Minister to exercise due diligence in respect of the information provided that contributed to the Government's lack of appreciation of the problem. I would characterize the information provided by Eastern Health as the truth - but not the whole truth. However, there was sufficient information provided by Eastern Health to the Department of Health and Community Services that, had due diligence been exercised, departmental officials would have realized that there was a difference in their understanding of what was to be publicly communicated and what was in fact communicated and that certain figures relating to the number of patients affected by ER/PR which were being provided to the Department just did not add up. What must also be noted is that in this process, the management of Eastern Health, the Department and the Minister effectively removed the Board of Trustees from all lines of communication.

The whole of the health system, to varying degrees can be said to have failed the ER/PR patients. There was a failure of both accountability and oversight at all levels.

Chapter Eighteen

Elizabeth Finlayson

Elizabeth Finlayson

The Story of a Mother and Daughter

That sounds like me

Ms. Elizabeth Finlayson is a resident of Wabush, Labrador. She and her daughter, Jane Hopkins testified together at the public hearings. Ms. Finlayson's story is particularly troubling in that there were so many occasions on which she fell through the cracks in the system.

Ms. Finlayson had a core biopsy taken and was diagnosed with breast cancer in St. John's on August 25, 2000. She underwent a mastectomy at the Captain William Jackman Memorial Hospital in Labrador City on October 2, 2000.¹ There is no pathology laboratory or pathologist in Labrador City. Thus, post-surgery her breast specimen was shipped from Labrador City to St. John's where her pathology was carried out. Her pathology report states that the specimen was received at the General Hospital laboratory in St. John's on October 6, 2000, four days after her surgery.

Ms. Finlayson was seen at the Cancer Centre on November 15, 2000. She came under the care of an internist. She was seen again at the Cancer Centre on November 22, when she had her first chemotherapy cycle. She was seen on November 24, 2005, by a radiation oncologist. During those visits there was no discussion of her hormone receptor status. In fact, at that time the results of Ms. Finlayson's hormone receptor test were not entered on her chart.

Ms. Finlayson returned to Labrador and the rest of her chemotherapy was administered by a nurse at the hospital in Labrador City.

On December 5, 2000, almost two months after Ms. Finlayson's original pathology had been carried out, the results of an ER/PR test were entered as an addendum to her pathology report. The results were ER negative and PR positive (40-50%). The evidence before the

¹ Exhibit C-0281, Operative Report.

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Commission is that oncologists in St. John's were making decisions regarding whether to offer anti-hormonal treatment on the basis of PR positivity as well as ER positivity. By that standard, Ms. Finlayson was hormone receptor positive in 2000. Unfortunately this was never brought to her attention and she was not offered anti-hormonal treatment at that time. No explanation has been offered to Ms. Finlayson by Eastern Health as to how the result of her ER/PR test could be entered on her chart without any subsequent follow-up by a physician.

Upon completion of her chemotherapy, Ms. Finlayson returned to St. John's on March 19, 2001, to undergo radiation therapy. She was treated at the Cancer Centre over the course of the next month. There was still no mention of her hormone receptor status or the option of anti-hormonal treatment, even though by now the results of her ER/PR test were on her chart. Upon completion of her radiation therapy on April 20, 2001, she returned to Labrador. Her radiation oncologist told her he would see her in Labrador in six months. She did not hear from him again. Over the next five years, Ms. Finlayson received no follow-up care from the Cancer Centre. Eastern Health has advised that oncologists from the Cancer Centre discontinued peripheral clinics in Labrador in 2001. Apparently no arrangements were made to transfer the care of Ms. Finlayson.

The ER/PR problem was discovered in 2005 and the massive re-testing of ER negative patients began. Even though Ms. Finlayson was originally ER negative, she was never identified for re-testing. Subsequent to the conclusion of the Inquiry's public hearings, Eastern Health advised that Ms. Finlayson had not been identified as she was one of the patients for whom no order for the ER/PR test was entered into the Meditech laboratory module.

In 2006, Ms. Finlayson developed a persistent cough. She spent nine days in hospital in Labrador in July 2006 for what was thought to be pneumonia. The cough persisted, and her family physician referred her to a specialist in St. John's in September 2006. She underwent further surgery at St. Clare's and was advised that her breast cancer had spread to her lungs. She was referred to the Cancer Centre and came under the

care of a medical oncologist. She was seen by the medical oncologist for the first time on September 29, 2006. The First Assessment Summary completed by her medical oncologist on that date notes that he had discussed Ms. Finlayson's case with breast pathologist Dr. Beverly Carter, who had reviewed the specimen and felt that it was consistent with the previous breast primary. The medical oncologist requested an ER/PR test and Her2/neu test. It is not clear if he was requesting that this testing be done on breast tissue from the original surgery in 2000 or the lung specimen from the recent surgery. In any event, it was a breast tissue specimen from her original surgery in 2000 that was sent by Dr. Carter to Mount Sinai on October 10, 2006. However, only a Her2/neu test was carried out; the ER/PR was not tested. Dr. Donald Cook entered the result of the Her2/neu test on her chart on October 17, 2006, as an addendum to the original pathology report. This report also contained, as an addendum, the ER/PR results from the original October 2000 test. Despite Dr. Cook's extensive involvement in the ER/PR review, apparently he did not notice that Ms. Finlayson's ER test had not been repeated at Mount Sinai. Furthermore, neither her medical oncologist nor Dr. Carter identified Ms. Finlayson as a patient who should have been re-tested as part of the ER/PR review.

In 2006 there was once again no discussion with Ms. Finlayson as to her hormone receptor status or the re-testing of patients. She was told that her disease was not curable but could be controlled and slowed down with further chemotherapy.

Ms. Finlayson returned home to Labrador to begin another round of chemotherapy. Her medical oncologist had noted on September 29, 2006, that if the ER/PR test that he had requested was positive and there was a good response to the chemotherapy, he would stop the chemotherapy after six cycles and treat with anti-hormonal drugs only. Unlike the aftermath of her treatment in 2000, this time Ms. Finlayson was followed up at the Cancer Centre. She was seen again six months later, on March 28, 2007, and for the first time the original ER/PR test is referred to in a Progress Note on her chart. How the test result came to the attention of her medical oncologist in the interim is uncertain. It certainly was not explained to Ms. Finlayson.

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Her chemotherapy was stopped and Ms. Finlayson began anti-hormonal treatment. She was not told that the decision to use anti-hormonal treatment was based upon an ER/PR test carried out in 2000, when she was first diagnosed. By this time, Ms. Finlayson's cancer had spread to her lungs and bones.

On July 5, 2007, Ms. Finlayson had an appointment via video conference with her medical oncologist. Ms. Finlayson and a nurse participated from the hospital in Labrador City, while the doctor participated from St. John's. On that date there was good news in that the anti-hormonal treatment appeared to be working. Several of her follow-up appointments since have taken place via video conference.

By the time she was seen again via video conference on February 28, 2008, the disease had progressed in her bones and there was a new lesion in her liver. Her anti-hormonal therapy was stopped and further chemotherapy was arranged.

Throughout this entire time, Ms. Finlayson remained unaware of the ER/PR issue. In late March 2008, she saw coverage of the public hearings of this Inquiry on television. She told her daughter that it "sounds like me" when she heard the situations of the patients testifying. Ms. Hopkins phoned Eastern Health and spoke with Ms. Nancy Parsons on March 27, 2008. The next day the two spoke again. Ms. Parsons made inquiries within Eastern Health about Ms. Finlayson and contacted Ms. Hopkins the next day. Ms. Parsons advised that Ms. Finlayson had never been re-tested and asked whether they wished that to be done. She also inquired whether they wished to have the re-test in St. John's or Toronto. If the latter option was chosen, it would take about six weeks. Ms. Hopkins replied that of course they would like Ms. Finlayson re-tested and asked that it be done in Toronto. Ms. Parsons indicated that someone from the Cancer Centre would follow up with Ms. Hopkins the following week.

Ms. Sharon Smith called Ms. Hopkins on April 10, 2008. Ms. Hopkins asked her why her mother had not been re-tested. Ms. Smith

could provide no answer. She did, however, make a note to check with the lab to see why Ms. Finlayson had not been re-tested. Ms. Hopkins also inquired as to why her mother had not been followed up by the Cancer Centre for the five-year period following her original diagnosis, and Ms. Smith replied that follow up is often with the family physician.

The re-test was carried out at Mount Sinai and entered on Ms. Finlayson's chart by Dr. Denic on April 15, 2008. On re-test her ER was 30% and her PR was 60%. It would, however, be almost another three months before those results were communicated to Ms. Finlayson. In the meantime, there was plenty of communication within Eastern Health about Ms. Finlayson's case. On April 29, 2008, Ms. Heather Predham emailed Ms. Pat Pilgrim, Ms. Smith, and Ms. Parsons with information on a couple of patients, including Ms. Finlayson. Ms. Predham wrote:

- Was originally ER negative PR 40-50 in 2000. Her daughter had called asking whether or not her mother was affected. The patient is still alive but very sick as she has lung metastases diagnosed in 2006. She was not identified for retesting originally
- Dr. Zulfigar saw her in 2006 and based on her 2000 ER/PR started her on Femara
- She was just retested at Mount Sinai and came back as ER 30 and PR 60
- She will have to be paneled ² (original emphasis)

Ms. Finlayson's treatment had already been changed by her treating oncologist based on her original PR positivity. She remained PR positive on re-testing and became ER positive. It is difficult to understand what benefit there would be to Ms, Finlayson to have her case paneled. It is inexcusable that communication to her of the results would be delayed pending the paneling process.

In late April 2008, having heard nothing from Eastern Health, Ms. Hopkins once again called Ms. Parsons. Ms. Parsons said that her mother's case would have to be paneled. By this time, Ms. Hopkins had been following the testimony at the Inquiry, so she understood that if the Panel were reviewing her case, it meant her results had changed.

² Exhibit C-0313.

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On May 15, 2008, Ms. Predham again emailed Ms. Pilgrim and Ms. Smith. She forwarded a list of patients, including Ms. Finlayson, who had come forward since the spring. She noted that Ms. Finlayson was to have been paneled and inquired as to whether that had happened.

On May 22, 2008, Ms. Hopkins again called Ms. Parsons to inquire as to the status of her mother's re-test. She was advised that the paneling session had been cancelled but would be going ahead the following week. A panel letter would then be sent to Ms. Finlayson's family physician in Wabush and Ms. Finlayson could obtain the results from him.

On June 5, 2008, Ms. Finlayson had her regular video-conference appointment with her medical oncologist. The nurse's notes of that call record that the results of Ms. Finlayson's ER/PR re-test are "yet unavailable" but will be discussed at her next visit. Ms. Finlayson recalls being told by her medical oncologist that day that her re-testing results were unavailable. The results, of course, had been entered on her chart since April 15, 2008. The Progress Note for the June 5, 2008, video-conference made no reference to any discussion about Ms. Finlayson's re-test. On the same day, Ms. Finlayson's case was reviewed by the Panel. The Panel, which was chaired by Dr. Laing, noted that Ms. Finlayson had received Femara for metastatic breast disease. Therefore, there was no recommendation for any change in treatment. A panel letter was then sent to her medical oncologist and copied to Ms. Finlayson's family physician. The letter provided the new test results and stated that the panel had no recommendation for a change in treatment, as Ms. Finlayson had received anti-hormonal treatment.

Ms. Finlayson visited her family physician and that is how she learned of her original test results and her re-test results. She was disappointed to see that her numbers had changed but she received no explanation as to what that meant. In fact, nobody has explained to her what the panel letter means in terms of her treatment. Ms. Hopkins took exception to the implication of this letter. To her it suggested that her mother had already received the appropriate treatment, but she had not

been placed on anti-hormonal treatment until after she was diagnosed with metastatic disease.

On July 2, 2008, her medical oncologist telephoned Ms. Finlayson to discuss the content of the panel letter. By this time, Ms. Finlayson had already received a copy of the panel letter from her family physician. Her medical oncologist told Ms. Finlayson that the “treatment philosophy” in her case had not changed. He told her the progesterone receptor was originally positive and had remained positive. She asked the obvious question: if that were the case, why was she not given any anti-hormonal treatment back in 2000? Her medical oncologist noted that he was unable to find any information in her chart of a discussion regarding hormone receptors and he could not answer her question. He said he would discuss it further with her when she came to St. John’s for a visit in August. Nothing is recorded in the Progress Note of any discussion that day regarding the re-test results.

On May 27, 2008, Eastern Health was preparing an apology letter to send to Ms. Finlayson. The letter was signed and Eastern Health’s records indicated that it was to be sent out the week of June 16, 2008. By July 3, 2008, the decision was made that no letter of apology was to be sent to Ms. Finlayson. Up to the time of her testimony, Ms. Finlayson had never received an apology from anyone at Eastern Health.

Ms. Finlayson’s case leaves many unanswered questions:

- Why were her original ER/PR result and the option of anti-hormonal therapy not discussed with her in 2000?
- Why was she not identified for re-testing in 2005? If it was because the order for the test was not filled out, how did that happen?
- Why in 2006 when she was diagnosed with metastatic disease was she still not identified to be re-tested?
- Why was it that when she was seen by her medical oncologist for the first time in September 2006, he seemed unaware of her original ER/PR test?

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- Why were the results of her re-test on her chart from April 15, 2008, and yet not communicated to her by anyone from Eastern Health until June 5, 2008, notwithstanding Eastern Health's knowledge that she was seeking those results?
- Why did Eastern Health choose to have Ms. Finlayson receive the results from her family physician in Labrador, although he would not have been familiar with the paneling process?
- Why was there a further delay of three months after the re-test in having the results communicated to Ms. Finlayson when Eastern Health was well aware she had already been delayed three years in being re-tested because she had been overlooked during the original re-testing process?
- Why in 2008, in the midst of this Inquiry, did Eastern Health continue to give priority to paneling Ms. Finlayson's case, as opposed to respecting the interests of its patient in communicating test results in a timely and effective manner?
- Why was she never offered an apology?
- Why was she never offered a face-to-face meeting to explain to her all of the things that went wrong in her case?
- Have there been occurrence reports completed for each of the occurrences in Ms. Finlayson's case? What has been done to address these issues?

Chapter Nineteen

Terms of Reference and Recommendations

Terms of Reference and Recommendations

- (a) *inquire into why the estrogen and progesterone hormone receptor tests done between 1997 and 2005 in the Newfoundland and Labrador health system resulted in a high rate of conversions when re-tested;*

In this term of reference, the Commission is directed to why there was a high rate of conversions on re-testing. The word “conversion” is not defined. I have assumed that conversion in this context has the same meaning as that given to it by Eastern Health in its communications with Government. That is, a conversion is a change in ER result from clinically negative on original testing to clinically positive on re-testing.

The response that follows does not address any particular patient’s circumstances. Rather, it reflects my opinion of the factors that contributed to the high rate of conversions. Stated in general terms, the primary causes of the changes in testing results were poor fixation and tissue processing, the absence of optimization of processes, the failure to follow proper procedures in ER/PR testing, and inadequate and/or improper antigen retrieval. Each of these factors, in turn, has a number of contributing factors. For example, poor fixation may be the result of improper handling of a specimen in the operating room, failure to place the specimen in the proper fixative, failure to follow proper grossing techniques in the appropriate time frame, or failure to leave the specimen in the fixative for the proper amount of time. These factors are discussed in the report. The high rate of conversions was caused by the lack of quality assurance processes in the IHC laboratory that could have prevented the problems or at least have detected them earlier, as well as the failure of pathologists to pay adequate attention to internal controls.

- (b) *inquire into why the problem with the estrogen and progesterone hormone receptor tests was not detected until 2005, whether it could have been detected at an earlier date, and whether testing protocols during that period between 1997 and 2005 were reasonable and appropriate;*

Two questions are raised by this Term of Reference: could the “problem” have been detected prior to 2005, and were the protocols “reasonable and appropriate” during the relevant period?

In my opinion, had proper quality assurance and quality control policies been in place and had they been followed, the problem with ER/PR testing would certainly have been discovered much earlier. In this context, I am referring to such measures as proper validation, the use of external proficiency testing, and attention being paid to internal controls by pathologists.

The most obvious example of a situation in which the problem could have been detected and perhaps, in fact, was detected occurred in 2003, around the time Dr. Ejeckam halted ER/PR testing. When asked why a re-examination of tests was not conducted at that time, Dr. Ejeckam said there was no index case. We now know that in the spring of 2003 there were a number of cases where patients’ results changed, much as Ms. Deane’s results changed in the spring of 2005. As in the Deane case, there were no occurrence reports filed respecting those cases. Had occurrence reports been filed, this, coupled with Dr. Ejeckam’s observations about the tests, as stated in his three 2003 memos, should have triggered a review at that time. Indeed, Dr. Banerjee was of the opinion that Dr. Ejeckam’s concerns alone should have triggered an external review in 2003. Even in 1999, the problem might have been detected had Ms. Purcell’s case been investigated, as Dr. Cook agrees it should have been.

The difference in 2005 was that Ms. Deane’s case was associated with her diagnosis and consequently it triggered consideration by oncologists of others with the same diagnosis or other diagnoses where one would generally expect a positive ER/PR result. That having been said, I am satisfied that for Ms. Deane, and patients like her with invasive lobular carcinoma, the original negative ER test results should have been questioned by both pathologists and oncologists. At a minimum, the ER/PR tests for such patients should have been redone. A number of our witnesses testified that the likelihood that an invasive lobular cancer would be ER positive was well known during the time period in

question. I am of the opinion that this information would not have been known only to a sub-specialist such as Dr. Clifford Hudis or Dr. Frances O'Malley.

In respect of ER/PR testing, no one was keeping track of the positivity rates, or any other metrics. Let me emphasize that positivity rates by themselves are not adequate quality assurance, as they do not reveal errors in an individual case. However, positivity rates can be a useful tool where there is a large-scale problem. Had ER/PR metrics been kept from 1997 to 2005, even on a yearly review it would have been obvious that in certain years the positivity rates were so outside the norm that laboratory staff should, in the normal course of events, have investigated to determine the source of the problems.

As to the second question, the procedures and protocols within Eastern Health for ER/PR testing during the period from 1997 to 2005 were so deficient as to be practically non-existent. They were neither reasonable nor appropriate.

- (c) *inquire into whether, once detected, the responsible authorities responded and communicated in a timely manner to those women and men who needed re-tests and those who were being tested for the first time;*

For the purpose of this Term of Reference, responsible authorities are the four regional health authorities in Newfoundland and Labrador. While the Minister of Health and Community Services and the Government of Newfoundland and Labrador are considered responsible authorities, they had no role to play, nor should they, in the contacting of patients regarding their test results.

The question, therefore, is whether the regional health authorities responded and communicated in a timely manner "to those women and men who needed re-tests and those who were being tested for the first time." The question is once again directed to the general response, not the response to each patient. I understand "once detected" in this context to mean 2005, when Ms. Deane's ER/PR test results changed on re-testing.

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The decision to re-test all the ER negative patients at Mount Sinai was made in August 2005. I am satisfied that this decision was timely. It was made following re-tests conducted in-house by Dr. Carter which demonstrated the magnitude of the problem.

With very few exceptions, prior to the ER/PR issue becoming public, patients were not advised of the fact that a re-test was to take place. Most of Eastern Health's patients had been identified by this time. Patients of other regional health authorities had not all been identified before October 2, 2005. I recognize that there would have been a minority of patients who might not wish to be informed of the re-test, but I am satisfied that the majority would not feel that way. An example is given in the testimony of Ms. Geraldine Rogers, who expressed the importance of communication at all stages in this process. By standards of the day, patients are encouraged to be well-informed and active participants in decisions regarding their care. They should have been informed as soon as practical after they were identified for retesting.

Generally, the patients whose test results had not changed were advised within a reasonable time after the results were emailed to St. John's. They were given their results by telephone. The time from receipt of re-test results to phone call varied somewhat with the number which were being returned at any one time.

For those who were paneled, however, the experience varied. Sometimes the Panel process itself caused delay in communicating with the responsible physicians, and therefore with the patient. This was particularly so for communication with patients who were diagnosed with DCIS and for those who were "retro-converters," as their paneling was postponed until it was decided how to deal with these patients. As well, patients who were paneled but for whom no change in treatment was recommended were often delayed in receiving their results, as medical oncologists had been advised that these patients did not need to be informed of their results until their next scheduled appointment at the Cancer Center. This could easily have resulted in delays of six months to a year because the regular scheduling of follow-up appointments

occurred at those intervals. Delays in timely communications with patients being paneled also occurred when discussion of particular patients was postponed because the panel did not have all required information concerning the patient (including instances when additional information had to be obtained from other regional health authorities). Sometimes, delays were caused to other patients when the Panel first assessed patients who had already been seen by an oncologist and had their treatment adjusted. This was an unnecessary step when there were many pending cases to be paneled.

Indirectly, the Panel process itself caused delays. Approximately 53% of panel letters were sent to physicians at the Cancer Center or surgeons who sat on the Panel. It seems these patients could have been dealt with by the individual physician identified on the letter without having to wait until they were reviewed by the Panel. If there were instances where these physicians wanted input from their colleagues on how to deal with a particular patient's case, it would seem to me that they could simply have sought this in the usual manner.

Communication with those women and men who needed re-tests was also often delayed by problematic information management. Not only were there serious problems with the ability of each regional health authority to identify patients who required re-testing, there were also problems identifying the proper (or any) physician to receive panel letters and/or results of the re-tests (addenda to pathology reports). In some cases, results were returned but the treating physician did not realize the re-test results had been entered on the patient's chart.

As the Panel dealt with patients from all over the province, the experience of persons who were patients of other regional health authorities was similar.

There was a witness who was tested for the first time as a result of the ER/PR matter. There was a delay of over two years before she learned the results of her test. Her story is recounted in the report. The Commission is not aware of any other persons who would fall into the category of persons who were being tested for the first time as a part of

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the re-test. The turn around time for prospective testing undertaken by Mount Sinai for the regional health authorities was considered to be satisfactory by the regional health authorities.

- (d) *inquire into whether, once detected, the responsible authorities communicated in an appropriate and timely manner with the general public and internally within the health system about the issues and circumstances surrounding the change in test results and the new testing procedures;*

For the purpose of this Term of Reference, responsible authorities are the four regional health authorities in Newfoundland and Labrador, as well as the Minister of Health and Community Services and the Government of Newfoundland and Labrador. They all had a greater or lesser role in communicating with the general public and each other about the ER/PR matter.

While Eastern Health communicated in a timely manner with other regional health authorities on matters related to the collection of tissue blocks for re-testing, the same cannot be said about the issues and circumstances surrounding the change in test results. The most blatant example of a failure by Eastern Health to communicate with other regional health authorities in an appropriate and timely manner was the failure to advise them of concerns related to the fixation of tissue, a matter of patient care equally important to the other regional health authorities. Eastern Health was also remiss in the manner it communicated information about the ER/PR investigation to the medical community at large - particularly physicians. Eastern Health failed to alert in a timely manner so as to allow physicians adequately to prepare to respond to the questions patients would inevitably pose after the matter became known to them. What little information Eastern Health did, in late 2005, provide to physicians was so limited in detail as to leave them in practice no better informed than the general public.

Eastern Health certainly failed in its duty to be forthright with Government, as on a number of occasions it withheld relevant information as to the extent and the cause of the problem from those

charged with political responsibility for the quality of health care in the province.

Eastern Health also failed in its communications with the media and public at large. The communications to the public minimized and obfuscated both the scope of the problem and the potential seriousness of its consequences for the patients affected.

Because their involvement in the investigation into the causes of the ER/PR problem was somewhat limited, the other three regional health authorities cannot be faulted for failing to communicate what Eastern Health omitted to tell them.

The Minister of Health and Community Services had an obligation to act in an oversight role. The respective Ministers routinely sought from Eastern Health information related to the problem. After September 30, 2005, they did so in a timely fashion. In 2007, as a result of the indiscriminate acceptance by the Minister of information provided to him by Eastern Health, he communicated to the public inaccurate information regarding patient contacts and the quality of laboratory services. The Minister's duty of due diligence demanded more.

As to new testing procedures, shortly after arrangements were made, Eastern Health advised the Minister that all current testing was to be done at Mount Sinai. That information was conveyed to other regional health authorities by late August and after October 2, 2005 it was made public.

(e) *advise whether the estrogen and progesterone hormone receptor testing systems and processes and quality assurance systems currently in place are reflective of "best practice";*

At present, estrogen and progesterone receptor testing is not being conducted within Newfoundland and Labrador. The Commission was advised, however, that Eastern Health hopes to re-establish this service in the near future. As ER/PR testing is not now being carried out at Eastern Health, it is not possible to provide the advice requested.

I can advise that at the conclusion of the Commission hearings, Eastern Health was in the process of developing new Procedure and Policy manuals. The portions which had been completed prior to a review, conducted in late September 2008 by two experts engaged by the Commission, were described as very well written, detailed, concise and easy to understand. It was the opinion of those experts, which I accept, that those sections of the manuals which had been completed were equal to and, in some cases, superior to those used by accredited laboratories in other jurisdictions. They also noted evidence of thorough documentation throughout the work process at both St. Clare's and the General Hospital. They wrote: "we have nothing but praise for the laboratory and the bench staff in adopting such an excellent and extensive QC documentation program. If the resulting QA activities are completed, documented and acted upon, the loop will be closed, resulting in an exemplary 'Total Quality' system."

In early October 2008, at the request of the Commission, a histology laboratory expert visited each of the other three regional health authorities. These laboratories produce the tissue blocks which are sent to Eastern Health for ER/PR testing. Older manuals were used in all three of those other regional health authorities' laboratories. Those manuals should be rewritten to meet accreditation standards. Deficiencies were noted in quality control and quality assurance procedures. While the actual production of ER/PR slides does not take place in those laboratories, work done there on the pre-analytical phase is crucial to ensuring best practice in the ER/PR testing procedure. In the discussion under Term (f) I shall address the questions raised by the reviews of these laboratories.

- (f) *make the recommendations that the commission of inquiry considers necessary and advisable relating directly to the matters of public concern referred to in paragraphs (a) and (e).*

I. “Best Practices” for Hormone Receptor Testing by Immunohistochemistry

1. As testing methodology and “best practice” continue to evolve as a result of improvements in technology and advances in research, it would not be appropriate to dictate how testing should be performed. The creation of the policies and procedures currently in place at Eastern Health was an important first step towards ensuring that its estrogen and progesterone hormone receptor testing systems and processes, and quality assurance systems reflect “best practice.” Eastern Health must identify who is responsible for continual monitoring of consensus statements issued on and research in the area of immunohistochemistry and ensuring appropriate modifications are made to the testing protocols.

II. Quality Assurance and Accountability

2. It is recommended that the Government of Newfoundland and Labrador create a position of Provincial Director of Pathology and Laboratory Services for the province. This position should exist within the Department of Health and Community Services and be independent of the regional health authorities. The Department should create a job description for this position that clearly outlines the duties and responsibilities, which should include:
 - i. assisting the regional health authorities in development of policies and procedures;
 - ii. encouraging a collaborative culture of quality within laboratory medicine;
 - iii. coordinating efforts amongst regional health authorities to ensure adequate pathology locums are available;
 - iv. facilitating the regional health authorities’ preparation for accreditation of laboratories;
 - v. coordinating educational opportunities and dissemination of information amongst pathologists throughout the province;

- vi. coordinating educational opportunities and dissemination of information amongst laboratory staff throughout the province, including technologists and pathology assistants;
- vii. promoting a high quality of pathology and laboratory services throughout the province;
- viii. creating a strategic plan for provincial recruitment and retention of pathologists and laboratory medicine technologists.

3. In recognition of the critical importance of “quality,” it is recommended that in each regional health authority there be a separate quality portfolio. A separate position of Vice-President Quality must be created to manage this portfolio. The individual in this position would have a multi-functional role that includes providing assistance to all departments in areas of quality assurance and quality control, and ensuring all policies and procedures relating to quality are being fully complied with. While risk management might fit within this portfolio, claims management should not be included.

4. It is recommended that the Government of Newfoundland and Labrador require each regional health authority to obtain a license in order to operate a laboratory. It is further recommended that as a condition of licensure, each regional health authority must participate in a recognized accreditation program for laboratories.¹ A national program would raise the standard of practice across the country. A national accreditation program, therefore, is the optimum method of accreditation. I recommend that the Government of Newfoundland and Labrador utilize best efforts to work with other provinces towards establishing a national accreditation program. In the interim, it is recommended that the province require, as a condition of license, that each regional health authority participate in a recognized laboratory

¹ It should be noted that on February 22, 2008, the Province announced \$100,000 of funding for planning associated with the establishment of a laboratory accreditation system, and that the Department of Health and Community Services is establishing a Quality Network team lead by the Department that will assess, among other things, quality initiatives to ensure laboratory standards exist across the health care system.

accreditation program to ensure that the laboratories within this province operate at the standard required for accreditation. All regional health authorities should have support for meeting these standards. Examples of support required are funding to bring the laboratories up to accreditation standards and assistance, the preparation of manuals and policies for practice. It is important to note here that the external laboratory accreditation program should be a complement to other external and internal approaches to proficiency testing and quality assurance.

5. Reports were prepared by Mr. Williams Parks and Mr. Bryan Hewlett on review of laboratories at each regional health authority.² It is recommended that each regional health authority implement the recommendations contained in the report related to that health authority. It is further recommended that each regional health authority examine the reports relating to other health authorities and implement any recommendations also relevant to their laboratories. For example, implementing a practice of further separating cassettes in the tissue processor as done at the Charles S. Curtis Memorial Hospital may be appropriate for laboratories at other regional health authorities.

6. It is recommended that each regional health authority establish morbidity and mortality (quality assurance) rounds for pathology; Eastern Health should also establish such rounds for medical oncology. Both Dr. McCarthy and Dr. Laing, in their testimony before the Commission, discussed the importance of these rounds to quality assurance. All pathologists and oncologists should be required to participate in such rounds as a condition of continued employment with the regional health authority; accommodations need to be made to allow participation by pathologists and oncologists who work in areas that would prevent them from physically attending.³ These accommodations could include the

² Exhibits P-3117, P-3366, P-3367, and P-3368.

³ I note that currently, all oncologists in the province of Newfoundland and Labrador are employed within Eastern Health.

use of teleconference or videoconference technology. Best practices for these rounds should be developed as soon as is practicable.

7. Pathologists and oncologists should be required to participate in multidisciplinary rounds. The regional health authority should be responsible for ensuring the development of best practices for these rounds. Quality assurance and quality control must be considered a mandatory part of the job of all clinicians.
8. Time required for participation in rounds should be considered when determining the number of pathologists and oncologists required for each institution so that physicians do not have to choose between day-to-day tasks and participation in the quality assurance process. This is consistent with the report of Dr. Maung to the Government of Newfoundland and Labrador in 2007.
9. It is highly desirable to collect all data required to maintain laboratory metrics for estrogen receptor and progesterone receptor test results.⁴ It is therefore recommended that each regional health authority designate a staff person who is responsible for tracking ER and PR metrics within the regional health authority. It is recommended that Eastern Health track metrics not only for its own patients, but also for results of all tests completed at the IHC laboratory. These numbers should be compiled, at a minimum, on an annual basis. All regional health authorities should provide reports containing this data to the Department of Health and Community Services. This data would be a valuable tool for detecting potential problems, although it is important to point out that, as Dr. Mullen told the Commission, waiting for a deviation from an expected percentage would not be the most prudent or expeditious way to detect problems. Investigations should still be

⁴ Examples of metrics which should be tracked include positivity rates, correlations between ER and PR positivity, and ER/PR results by type of cancer. Dr. Brendan Mullen, of Mount Sinai Hospital, described his tracking of positivity rates, which he runs approximately every six months to ensure there are no deviations from accepted rates in his laboratory. Dr. David Dabbs also discussed the importance of using metrics, and suggested using positivity rates for ER in breast cancer as a benchmark for laboratories to monitor.

triggered based on individual cases that deviate from the norm, since to misdiagnose or misinterpret one test result affects patient care substantially.

10. It is recommended that information collected by regional health authorities relating to quality control and quality assurance within their laboratories be used appropriately to take corrective actions to prevent occurrences from happening. This information should be kept in electronic format for more effective usage and analysis of the information.
11. It is recommended that all regional health authorities utilize proficiency testing within their laboratories. The quality and safety framework within each regional health authority should include a regular schedule of internal and external audits, and these audits must cover all aspects of work being performed in the pathology laboratories. Internal reviews, such as the exchanges that have been conducted between Grand Falls and Gander,⁵ and Carbonear and Clarenville,⁶ should be encouraged and continued. Other regions should consider setting up similar exchanges.
12. I note that Eastern Health is in the process of implementing an electronic occurrence reporting system. All other regional health authorities should implement a similar system, with co-operation and coordination among all four regional health authorities to ensure the system is utilized to its full potential and that information gained within each authority can benefit all health authorities and prevent the repeating of similar adverse events.
13. Eastern Health, as mentioned above, has created standard operating policies and procedures for their laboratory. All other regional health authorities should ensure that standard laboratory operating procedures are in place, that staff are made aware of these procedures, and that a process is in place to ensure

⁵ Transcript of testimony, Dr. Barry Gallagher, July 25, 2008, p. 24-25.

⁶ Transcript of testimony, Dr. Gary Baker, September 5, 2008, p. 244-247.

compliance. These policies should also contain provisions to ensure they are regularly reviewed and updated.

14. It is recommended that there be an assessment to identify upgrades required to the laboratory premises and laboratory equipment within the Central, Western, and Labrador-Grenfell Regional Health Authorities. Resources needed to complete required expansion or upgrades to prepare these laboratories for the accreditation processes should be provided.
15. At the time of the review of Mr. Parks and Mr. Hewlett, a noticeable disconnect existed between individual work areas within the histology laboratory at Eastern Health and the management goals. Dr. Banerjee also noted in his initial report that “superior outcomes could be achieved by ensuring better linkages between technical, managerial and medical leadership.”⁷ Accountability has to be clear; the reporting structure within the Laboratory Medicine Program of Eastern Health must reflect the requirement of interaction between technologists and physicians to ensure best possible quality assurance outcomes. I recommend leadership training for management within the pathology division of the Laboratory Medicine Program.

III. Laboratory Technologists: Training and Continuing Education

16. As noted in the report of Mr. Hewlett and Mr. Parks, staff in the laboratory is in constant flux, which is counterproductive to a motivated, highly skilled, and productive technologist work force. While Eastern Health has dedicated three technologists to the IHC service, a succession plan should be implemented to minimize future attrition problems. The Canadian Society for Medical Laboratory Science states that a shortage of medical laboratory technologists will occur as large numbers of medical laboratory technologists retire over the next five to ten years. This shortage must be addressed so that patient waiting times, and therefore

⁷ Exhibit P-0046; Transcript of testimony, Dr. Diponkar Banerjee, July 30, 2008, pp. 155-160, 308-310.

timely access to appropriate treatment, are not adversely affected. The Department of Health and Community Services should carry out an analysis of requirements for medical laboratory technologists within the province for the foreseeable future and take steps to address any potential shortage. Addressing any potential shortage of medical laboratory technologists must not be accomplished by lowering the standards for admission into the training program.

17. With advances in technology and knowledge in the area of immunohistochemistry, highly skilled laboratory staff will be required to implement successfully new protocols and procedures. Eastern Health must develop, maintain, and update as appropriate all job descriptions for both technical and medical staff working in the IHC laboratory.
18. Eastern Health should develop formal in-house training programs for new immunohistochemistry technologists. Until these training programs are developed and implemented, Eastern Health should retain outside expertise to attend at its IHC laboratory to train the new staff. As a less desirable alternative, new staff could be sent for training to a laboratory that already has an acceptable training program in place. It is helpful to refer to the testimony of Ms. Maria Tracey on orientation and training for operating room nurses. The strict approach developed and followed for the nursing peri-operative program should be applied to laboratory technology staff, as these positions are also extremely important to safe and accurate patient care. Reference should also be made to the testimony of Ms. Patricia Wegrynowski, Mr. William Parks, and Mr. Bryan Hewlett relating to training required for laboratory staff at their respective institutions.
19. To ensure continuing quality within pathology laboratories, it is recommended that histology and IHC laboratory technologists be required to demonstrate their competency, at a minimum, on an annual basis. All regional health authorities must conduct annual

performance evaluations of histology and IHC technical staff and managers.⁸

20. All immunohistochemistry and histology laboratory technologists should be required to complete mandatory continuing education each year. Continuing education is vital in any area that continues to have new developments, particularly laboratory medicine. Regional health authorities should work cooperatively on this to ensure resources are maximized. Technologists should also be encouraged to complete online courses.⁹ Regional health authorities should support this effort by providing staff with the time required to complete the courses and the funding to pay for them.
21. The Laboratory Medicine Program at Eastern Health in setting its annual goals and objectives should place a greater emphasis on investment in human resources. This would assist in creating an environment that attracts and maintains highly qualified staff, and encourage their ongoing professional growth. In their review of Eastern Health laboratories, Mr. Parks and Mr. Hewlett noted that implementing new technologies requires not only purchasing new equipment, but also a “strong core group of experienced technologists with intimate knowledge and deep understanding of the current technology and willingness to learn and apply the new technology. The application of any new technology without this experience, knowledge and understanding can have dire consequences.”
22. It is recommended that the legislation currently being developed for licensing and regulation of medical laboratory technologists be completed as soon as is practicable.

⁸ Again, it is recognized that at present, IHC is only performed in St. John’s.

⁹ For example, those available through the Canadian Society for Medical Laboratory Science (CSMLS), as well as lectures and seminars offered under the sponsorship of the Newfoundland and Labrador Society of Laboratory Technologists (NSMLT).

IV. Physicians: Recruitment, Retention, Sub-specialization, Continuing Education and Supervision

23. While the province has substantially increased the benefit package available to pathologists in this province, there must be a plan developed to ensure the sustainability of this professional group. With respect to recruitment, the Department of Health and Community Services should develop a contingency plan for the establishment of pathology services in the event that an adequate number of qualified pathologists cannot be recruited and retained in all provincial hospital laboratories. Particular emphasis should be given to recruitment efforts in rural areas to allow “respite” for pathologists who work alone in institutions and have no colleague to relieve them. To this end, the Department of Health and Community Services should develop and implement a system to ensure adequate locums are available for pathologists. The Department of Health and Community Services should also implement a system to assess pathology manpower requirements on an ongoing basis. The regional health authorities must also continue to ensure recruitment and retention of pathologists is given high priority.
24. The Department of Health and Community Services and the regional health authorities should work together to explore alternative means of providing pathology services within the province and assistance to pathologists in their practice. It is recommended that a program be implemented to provide pathologists who work alone with a means for receiving feedback, advice, and interaction from colleagues. The Department of Health and Community Services should also ensure that adequate resources are available to fund technical resources such as telemedicine technology, particularly for pathologists who work alone, as well as new technology in the field of pathology digital imaging and computer transmission.
25. The Department of Health and Community Services should investigate and study the potential for the expansion of services

that could be provided by pathology assistants to laboratories in the province.

26. Pathologists should have a positive obligation to identify and inform their superiors when they have inadequate experience or any limitation in their ability or expertise with respect to performing a particular test or in assessing any particular case.
27. Continuing medical education for pathologists and oncologists must be mandatory and funded. Each regional health authority should develop a written protocol for continuing education for pathologists and oncologists in accordance with the requirements of the region. Each regional health authority has the responsibility to ensure the protocol is followed, and that adequate protected time and resources for these physicians is provided to allow them to participate.
28. It is recommended that the appropriate person within each regional health authority complete an annual performance review of the work of each pathologist and oncologist. The regional health authority is responsible for ensuring these reviews are completed.
29. It is recommended that the Royal College of Physicians and Surgeons of Canada consider expanding opportunities for sub-specialization within pathology.
30. Given the shortage of pathologists, faculties of Medicine are encouraged to promote interest in pathology as a specialty by exposing students to pathology in the early years of their program. Faculties of Medicine are also encouraged to expand their curriculum to ensure all medical students are educated as to the important, underlying role of pathology in the practice of medicine.

V. Crisis Management

31. Each regional health authority must develop and maintain a crisis management plan. Elements of a crisis management plan must include:
- i. a clear articulation of the roles of those managing the crisis;
 - ii. information management and record keeping;
 - iii. the role of the Board of Trustees;
 - iv. identification of special skills required to manage the crisis;
 - v. provision for notification of the Minister responsible under the *Regional Health Authorities Act*;
 - vi. a plan for communications, which would include with whom one should communicate, when communications should occur, and the method used to communicate;
 - vii. a conflict of interest policy.
32. Regional health authorities should develop a protocol for management of multi-regional crises.

VI. Legislation

33. It is recommended that the Government of Newfoundland and Labrador consider whether section 8.1 of the *Evidence Act*¹⁰ remains relevant.
34. It is recommended that any conflict between section 8.1 of the *Evidence Act* and section 12 of the *Public Inquiries Act, 2006*¹¹ be resolved in favour of permitting Commissions of Inquiry to have access to peer review and quality assurance reports.
35. It is further recommended that legislation be enacted to specify that adverse event disclosure to patients include an explanation of

¹⁰ RSNL1990, c. E-16.

¹¹ SNL2006, c. P-38.1.

why the adverse event occurred and what is being done to ensure that a similar event does not occur in the future. Disclosure should also involve providing the patient with a copy of any peer review or quality assurance report respecting the adverse event. As explained in this Report, the names of the individuals who participated in the peer review or quality assurance may be removed prior to disclosure. I recommend that these rights be entrenched in legislation and that they be given priority over any prohibition contained in section 8.1 of the *Evidence Act*.

36. It is recommended that the Government of Newfoundland and Labrador adopt apology legislation. While in many cases professionals do not need the protection of legislation to allow them to apologize, many experts have recognized the importance of apologies to both the care provider and the patient.

VII. Information Management

37. The Department of Health and Community Services should conduct a province-wide assessment of the information management needs of the regional health authorities. The communication problems that became evident during the ER/PR issue demonstrate why it is essential that this be done on a province-wide basis. Following this assessment of information management needs, any system chosen for data management should be capable of such things as:
 - i. ensuring that the results and reports of all diagnostic and treatment services referred by a physician to a regional health authority laboratory are transmitted to the treating physician in a timely manner;
 - ii. creating reminders within the laboratory when requested work has not been completed on a timely basis;
 - iii. tracking reports back to the physician who requisitioned them and confirming that reports are received and opened. If reports are not opened within a set period of time, the system should flag

- the report and send it back to the originating laboratory for follow-up;
 - iv. creating a reminder, after a certain period of time passes, that a report has not been returned when a consult was sent to an external institution;
 - v. communicating amongst regional health authorities.
38. The Cancer Care Program must develop and implement policies and procedures to ensure treating physicians receive all information concerning their patients in order to ensure timely and safe patient care.
39. A province-wide Electronic Medical Record system must be developed and implemented, including support for all regions and all physicians to have appropriate access to the system.
40. When one regional health authority is performing work referred from another regional health authority, there must be an obligation to share any information relevant to that work. The Provincial Director for Pathology and Laboratory Medicine should coordinate collaboration amongst laboratories to enhance overall quality of service.
41. Each regional health authority is responsible for the maintenance of a record-keeping system which enables responsible physicians to easily access and search all information required for safe and timely patient care. As valuable as the Cancer Registry is for the functions for which it was established, health authorities cannot abrogate responsibility for information management by virtue of the fact that the Cancer Registry exists.

VIII. Further Investigation

42. I agree with the review of positive cases currently being undertaken by Eastern Health where re-test results could potentially change a patient's original decision relating to the use

of anti-hormonal therapy. A similar review should be undertaken in each of the other regional health authorities.

43. It is recommended that the Department of Health and Community Services engage consultants external to the regional health authorities to assist with the investigation and decision as to what action, if any, is required for the remaining patients who originally had ER positive test results and, to date, have not been re-tested. This analysis should be undertaken with a view both to patient care and to obtaining as much information as possible about the circumstances which gave rise to the ER/PR problem. The decision as to whether further testing is required rests with the Department of Health and Community Services upon receipt of the consultant's report.
44. It is recommended that the regional health authorities identify all patients who have already been re-tested and whose hormone receptor status changed from "positive" to "negative" on re-test, and that an analysis be conducted to ensure that each such individual case has been reviewed to determine whether patients were appropriately treated and have been advised of their changed hormone receptor status.
45. Given the ambiguity surrounding the contact of the patients from Saint-Pierre and Miquelon, it is recommended that further investigation be undertaken by Eastern Health to ensure that all patients have been contacted.
46. It is recommended that an audit be conducted of the work of the pathologists who were identified through the ER/PR re-testing process as having interpreted background staining incorrectly as nuclear staining. Dr. Dabbs and Dr. Torlakovic recommended that an audit occur in such circumstances.
47. Only specimens from patients with primary breast cancer were candidates for the re-testing process commenced in 2005. There were non-primary breast cancer patients who had ER/PR testing

performed between 1997 and 2005 and therefore did not have their specimens re-tested. It is recommended that a review be undertaken by an external expert to determine what the ER/PR test was utilized for in those cases and whether, in the best interest of these patients, re-testing of their specimens is warranted. If the expert recommends re-testing of those specimens, the regional health authority responsible for each patient must arrange for the re-testing at the earliest possible time.

48. It is recommended that all reasonable efforts be made to identify and contact next of kin of the deceased patients whose specimens were re-tested as part of the ER/PR review. The regional health authority responsible for each of these patients should send letters to the next of kin advising that re-testing results are available and providing contact information to obtain the results should they wish to do so.
49. It is recommended that the Department of Health and Community Services engage the Newfoundland and Labrador Centre for Health Information to undertake further investigation as to whether any other use could or should be made of the data that was retrieved by the Commission from the DAKO Autostainer. As well, an analysis should be undertaken to determine whether the data can provide any useful information on the cause of the changed results, such as whether there is any correlation between changed test results and particular runs or particular dates.
50. It is recommended that data from the ER/PR re-testing review, including any subsequent reviews carried out pursuant to these recommendations, be collected and analyzed to obtain all useful information from this event. As there is a dearth of studies on this issue, review and analysis of available data presents an opportunity for research to be carried out. For example, patients who were placed on anti-hormonal treatment following changes in their ER/PR results should be followed and data collected to determine the efficacy of treatment initiated at various times post-diagnosis.

IX. Disclosure and Communications

51. All regional health authorities should have a policy to deal with disclosure of adverse events. Disclosure relating to adverse events should include:
- i. the facts;
 - ii. the actual or potential impact of the event on the patient;
 - iii. an expression of sympathy or regret;
 - iv. an overview of the process that will follow;
 - v. an explanation of why the event occurred;
 - vi. what is being done to ensure that a similar event does not occur in the future;
 - vii. whether a review has been conducted: if so, the patient is to be provided with a copy of any reports emanating from the review, if requested;
 - viii. an offer of future meetings;
 - ix. time for questions;
 - x. offers of support.
52. The skills for communicating with patients about adverse events can be learned. Physicians should be trained in disclosure of adverse events. The training of physicians should include not only patient disclosure, but also patient safety and quality assurance practices. This training should be part of continuing medical education.
53. It is also important that staff involved in disclosure of adverse events to patients have the skill and knowledge to do so. The regional health authorities should identify the appropriate persons to conduct disclosure, what support these individuals need, how best to educate them as to the particulars of occurrences, what they should convey to the patients, and the health authority's disclosure policy.

54. It is recommended that for ethics consultations occurring within regional health authorities, priority be given to ensuring there is balance of perspectives amongst those participating. If the consultation is dealing with disclosure to patients, the presence of a person or persons who can articulate and advocate for the position of patients is required.
55. It is recommended that each regional health authority's disclosure policies be reviewed periodically to ensure compliance with current standards. Audits should be undertaken by each regional health authority to ensure that policies are current and that staff are aware of and comply with policies.
56. It is recommended that the regional health authorities post policies and procedures relevant to disclosure and patient safety on their respective websites and make them available to the public on request. To demonstrate their commitment to the principle of transparency and to assist in rebuilding public confidence in the healthcare system, any assessment or accreditation of the regional health authority relating to patient safety indicators should also be posted on the website and made available to the public.
57. All regional health authorities must preserve communications related to an adverse event, including all forms of electronic communication. Each regional health authority should develop a policy to that effect and educate its staff as to the importance of adhering to the policy.
58. "Patient navigator" positions should be created within each hospital. The primary responsibility of the patient navigator would be to communicate with and on behalf of the patient. These individuals would, among other things, assist patients and/or their families in dealing or communicating with the hospital.

X. Implementation and Review of the Recommendations

59. The Government of Newfoundland and Labrador should provide sufficient funding to implement the recommendations contained in this report.

60. The Minister of Health and Community Services should report to the House of Assembly on the status of implementation of the recommendations contained in this report by March 31, 2010.

Glossary of Terms

Acronyms and Abbreviations

Glossary of Terms

Accountability	the obligation to answer for a responsibility conferred. When called on to account, a party on whom responsibility has been conferred must explain and justify – against criteria of some kind – his or her decisions or actions. (<i>Goudge Report</i>)
Accreditation	of an official body, give authority or sanction to (someone or something) when recognized standards have been met. (<i>Oxford</i>)
Affinity	a special attraction for a specific element, organ, or structure. (<i>Dorland's Illustrated Medical Dictionary</i>)
Allred score	a semi-quantitative scoring system that was developed by Craig Allred, the senior pathologist in the Baylor group and it comprises of two components. There's a proportion score and an intensity score. (<i>Transcript of testimony, Dr. Frances O'Malley Trans. June 23, 2008, p. 36</i>)
Anatomic Pathology	the anatomical study of changes in the function, structure, or appearance of organs or tissues, including post mortem examinations and the study of biopsy specimens. Called also morbid or pathological anatomy and pathoanatomy. (<i>Dorland's Illustrated Medical Dictionary</i>)
Antibody	an immunoglobulin molecule that has a specific amino acid sequence by virtue of which it interacts only with the antigen that induced its synthesis in cells of the lymphoid series (especially plasma cells), or with antigen closely related to it. Antibodies are classified in groups named according to their mode of action, such as agglutinins, bacteriolysins, hemolysins, opsonins, precipitins, and others. (<i>Dorland's Illustrated Medical Dictionary</i>)
Antigen	any substance capable, under appropriate conditions, of inducing a specific immune response

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and of reacting with the products of that response, that is, with specific antibody or specifically sensitized T lymphocytes, or both. (*Dorland's Illustrated Medical Dictionary*)

Antigen retrieval

antigen retrieval (or antigen recovery) is performed to expose or retrieve antigens which have become masked by the tissue fixation process. (<http://www.histochem.net>)

Arimidex

trademark for a preparation of anastrozole. A nonsteroidal aromatase inhibitor that lowers levels of serum estradiol by interfering with its production in peripheral tissues and is used in chemotherapy for advanced carcinoma of the breast in postmenopausal women; administered orally. (*Dorland's Illustrated Medical Dictionary*)

Assay

determination of the amount of a particular constituent of a mixture, or determination of the biological or pharmacological potency of a drug. (*Dorland's Illustrated Medical Dictionary*)

Benign

not malignant; not recurrent; favourable for recovery. (*Dorland's Illustrated Medical Dictionary*)

Bimodal Curve

having two modes; of a graph, having two maxima. (*Dorland's Illustrated Medical Dictionary*)

Biopsy

the removal of a sample of tissue from a living person for laboratory medicine. (*Goudge Report*)

Biotin

a water soluble B-complex vitamin and avidin is a protein derived from egg white which has a strong affinity for biotin. Streptavidin is a highly stable analogue of avidin. (*Exhibit P-1425, p.15*)

Block

a term used to describe tissue that has been processed and embedded in paraffin wax. The creation of a block from the tissue specimen allows the tissue to be manipulated and properly oriented for sectioning to create slides that are then used in the immunohistochemical process.

Blocking	interfering with afferent nerve impulses; see regional anesthesia, under anesthesia. (<i>Dorland's Illustrated Medical Dictionary</i>)
Briefing Note	briefing notes are intended to provide the Premier/Minister/Senior Executive with an at-a-glance clear understanding of a specific issue, as well as a suggested approach to addressing the issue publicly by focusing on key messages. (<i>Exhibit P-0123, p. 3</i>)
Calibrate	1. Mark a (gauge or instrument) with a standard scale of readings. 2. Correlate the readings of (an instrument) with those of a standard in order to check the instrument's accuracy. 3. Adjust (experimental results) to take external factors into account or to allow comparison with other data. (<i>Oxford</i>)
Cancer	a neoplastic disease the natural course of which is fatal. Cancer cells, unlike benign tumor cells, exhibit the properties of invasion and metastasis and are highly anaplastic. Cancer includes the two broad categories of carcinoma and sarcoma, but in normal usage it is often used synonymously with carcinoma. (<i>Dorland's Illustrated Medical Dictionary</i>)
Carcinogen	any cancer-producing substance. (<i>Dorland's Illustrated Medical Dictionary</i>)
Chromatin	the complex of nucleic acids (DNA and RNA) and proteins (primarily histones, but also nonhistone proteins) in the eukaryotic cell nucleus, comprising the chromosomes (q.v.). See also euchromatin and heterochromatin. (<i>Dorland's Illustrated Medical Dictionary</i>)
Control	1. The governing or limitation of certain objects or events. 2. A standard against which experimental observations may be evaluated; see negative c. and positive c. (<i>Dorland's Illustrated Medical Dictionary</i>)
Conversion	a conversion was a change in ER result from clinically negative on original testing to clinically

positive on re-testing.

Convert	change the form, character or function of something. <i>(Oxford)</i>
Core Biopsy	needle biopsy with a large hollow needle that extracts a core of tissue; used in diagnosis of prostate and kidney conditions. <i>(Dorland's Illustrated Medical Dictionary)</i>
Cytoplasm	the protoplasm of a cell exclusive of that of the nucleus; it consists of a continuous aqueous solution (cytosol) and the organelles and inclusions suspended in it and is the site of most of the chemical activities of the cell. Cf. nucleoplasm. <i>(Dorland's Illustrated Medical Dictionary)</i>
DAKO Autostainer	an automated slide processing system for the staining of paraffin-embedded and frozen tissue sections (among other things) designed to automate manual staining methods routinely used in immunohistochemistry and other processes. This machine also allows optimization of protocols. <i>(www.dakousa.com)</i>
Diagnosis	1. The determination of the nature of a case of disease. 2. The art of distinguishing one disease from another. <i>(Dorland's Illustrated Medical Dictionary)</i>
Emulsion	a mixture of two immiscible liquids, one being distributed in small globules throughout the body of the second. It is a colloid system in which both the dispersed phase and the dispersion medium are liquids, the dispersed liquid being the discontinuous phase and the dispersion medium the continuous phase. <i>(Dorland's Illustrated Medical Dictionary)</i>
Endogenous	1. Growing from within. 2. Developing or originating within the organism, or arising from causes within the organism. Also called endogenic. <i>(Dorland's Illustrated Medical Dictionary)</i>
Enzyme	a protein molecule that catalyzes chemical reactions of other substances without itself being destroyed or

- altered upon completion of the reactions. Symbol E. Enzymes are classified according to the recommendations of the Nomenclature Committee of the International Union of Biochemistry. Each enzyme is assigned a recommended name and an Enzyme Commission (EC) number. They are divided into six main groups: oxidoreductases, transferases, hydrolases, lyases, isomerases, and ligases. For individual enzymes, see under the specific name, e.g. glucose-6-phosphate dehydrogenase. (*Dorland's Illustrated Medical Dictionary*)
- Epitope** antigenic determinant, a site on the surface of an antigen molecule to which a single antibody molecule binds; generally an antigen has several or many different antigenic determinants and reacts with antibodies of many different specificities. Called also epitope. (*Dorland's Illustrated Medical Dictionary*)
- Estrogen (oestrogen)** a generic term for any estrus-producing steroid. In humans estrogens are formed in the ovary, possibly the adrenal cortex, the testis, and the fetoplacental unit and have various functions in both sexes. (*Dorland's Illustrated Medical Dictionary*)
- Ethylenediaminetetraacetic acid (EDTA)** a commonly used buffer solution; (*Transcript of testimony, Kenneth Green, July 9, 2008, p. 74-78*)
- Femara** FEMARA (letrozole tablets) is approved for the adjuvant treatment of postmenopausal women with hormone receptor-positive early breast cancer. (*www.femara.com*)
- Fixation** the act or operation of holding, suturing, or fastening in a fixed position. (*Dorland's Illustrated Medical Dictionary*)
- Fixative** a fluid, often a mixture of several reactive chemicals, into which histological or cytological specimens are placed so that, by processes such as denaturation and cross-linking of proteins, autolysis is prevented, the specimen is hardened to withstand further processing, and the specimen is preserved in a close facsimile of the living state in regard to both cellular morphology and the location of subcellular

constituents. (*Dorland's Illustrated Medical Dictionary*)

Fluorescein

a yellow or red crystalline dye $C_{20}H_{12}O_5$ with a bright yellow-green fluorescence in alkaline solution that is used as the sodium salt to aid in diagnosis (as of lesions and foreign bodies in the cornea or of brain tumors); fluorescence - luminescence that is caused by the absorption of radiation at one wavelength followed by nearly immediate reradiation usually at a different wavelength and that ceases almost immediately when the incident radiation stops; also : the radiation emitted; luminescence - the emission of light. (*Medline Dictionary*)

Fluorescence microscopy

microscopy of natural fluorescent materials or of specimens stained with fluorochromes, which emit light when exposed to blue light or ultraviolet radiation. (*Dorland's Illustrated Medical Dictionary*)

Formalin

a formaldehyde solution; a solution of formaldehyde in water, containing not less than 37 per cent of formaldehyde; used as a disinfectant and as a preservative and fixative for pathologic specimens. Called also formol. (*Dorland's Illustrated Medical Dictionary*)

Gross

1. Coarse or large. 2. Visible to the naked eye without the use of magnification; called also macroscopic. (*Dorland's Illustrated Medical Dictionary*)

Her2/neu

HER2/ neu (also known as ErbB-2, *ERBB2*) stands for "Human Epidermal growth factor Receptor 2" and is a protein giving higher aggressiveness in breast cancers. It is a member of the ErbB protein family, more commonly known as the epidermal growth factor receptor family. HER2/ neu has also been designated as CD340 (cluster of differentiation 340).

Herceptin

trademark for a preparation of trastuzumab - a recombinant DNA-derived humanized monoclonal antibody that binds to human growth factor receptor 2 (HER2), a protein overexpressed in some breast cancers; used as an antineoplastic in the treatment of metastatic breast cancer with overexpression of HER2, administered intravenously. (*Dorland's Illustrated*

Medical Dictionary)

- Histochemistry** that branch of histology which deals with the identification of chemical components in cells and tissues. (*Dorland's Illustrated Medical Dictionary*)
- Histology** that department of anatomy which deals with the minute structure, composition, and function of the tissues; called also microscopic anatomy. Normal histology is the histology of normal tissues; pathologic histology is the histology of diseased tissues, also called histopathology. (*Dorland's Illustrated Medical Dictionary*)
- Homogenize** to render homogeneous, or of uniform quality or consistency throughout. (*Dorland's Illustrated Medical Dictionary*)
- Horseradish Peroxidase (HRP)** peroxidase EC 1.11.1.7 (q.v.) isolated from horseradish (*Armoracia lappathifolia*); used as a reagent in biochemical assays. (*Dorland's Illustrated Medical Dictionary*)
- Ig** immunoglobulin. The five classes are designated IgM, IgG, IgA, IgD, IgE. Subclasses are designated by numerical suffixes, e.g., IgG1. (*Dorland's Illustrated Medical Dictionary*)
- Immunofluorescence** any immunohistochemical method using antibody labeled with a fluorescent dye; called direct if a specific antibody or antiserum is conjugated with a fluorochrome and used as a specific fluorescent stain and indirect if the fluorochrome is attached to an antiglobulin, and a tissue constituent is stained using an unlabeled specific antibody and the labeled antiglobulin, which binds the unlabeled antibody. (*Dorland's Illustrated Medical Dictionary*)
- Immunohistochemical Stains** chemicals used in immunohistochemistry that colour through chemical processes and are used to analyze cells and tissues.
- Immunohistochemistry** of or relating to the application of histochemical and immunologic methods to chemical analysis of living cells and tissues. (*Medline Dictionary*)

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Immunoperoxidase	pertaining to immunocytochemical methods using antibody coupled to the enzyme peroxidase to stain tissue constituents; frequently used to identify tissue antigens to aid diagnosis in surgical pathology. <i>(Dorland's Illustrated Medical Dictionary)</i>
Infiltrating Lobular Carcinoma	a malignant new growth made up of epithelial cells tending to infiltrate the surrounding tissues and give rise to metastases. <i>(Dorland's Illustrated Medical Dictionary)</i>
Internal Control	tissue or cells in the same section or a separate section from the same patient specimen as the test section. <i>(Transcript of testimony, Dr. David Dabbs, September 15, 2008, p. 174)</i>
Invasive	1. Pertaining to or characterized by invasion. 2. involving puncture or incision of the skin or insertion of an instrument or foreign material into the body; said of diagnostic techniques. <i>(Dorland's Illustrated Medical Dictionary)</i>
Laboratory Medicine	a program within a health care organization that involves the collection and analysis of patient samples
Lumpectomy	1. Surgical excision of only the palpable lesion in carcinoma of the breast; called also tyelectomy. 2. surgical removal of a mass. Cf. excisional biopsy. <i>(Dorland's Illustrated Medical Dictionary)</i>
Malignant	1. tending to become progressively worse and to result in death. 2. having the properties of anaplasia, invasion, and metastasis; said of tumors. <i>(Dorland's Illustrated Medical Dictionary)</i>
Mammogram	a radiograph of the breast. Radiography - the making of film records (radiographs) of internal structures of the body by passage of x-rays or gamma rays through the body to act on specially sensitized film. <i>(Dorland's Illustrated Medical Dictionary; Transcript of testimony, Dr. Frances O'Malley, June 23rd, 2008, p. 24).</i>
Mastectomy	excision of the breast; called also mamnectomy. <i>(Dorland's Illustrated Medical Dictionary)</i>

Meditech	a software system (Health Information System) designed to assist health care organizations to integrate care delivery through management of data; it consists of many different components, some of which were used by Healthcare/ Eastern Health and the other three regional health authorities in Newfoundland and Labrador. (<i>www.meditech.com</i>)
Metastasis	1. The transfer of disease from one organ or part to another not directly connected with it. It may be due either to the transfer of pathogenic microorganisms (e.g. tubercle bacilli) or to transfer of cells, as in malignant tumors. The capacity to metastasize is a characteristic of all malignant tumors. 2. pl. metastases. A growth of pathogenic microorganisms or of abnormal cells distant from the site primarily involved by the morbid process. (<i>Dorland's Illustrated Medical Dictionary</i>)
Microscope	an instrument used to obtain an enlarged image of small objects and reveal details of structure not otherwise distinguishable. (<i>Dorland's Illustrated Medical Dictionary</i>)
Microtome	an instrument for cutting thin slices of tissue for microscopical study. (<i>Dorland's Illustrated Medical Dictionary</i>)
Monoclonal	derived from or pertaining to a single clone. (<i>Dorland's Illustrated Medical Dictionary</i>)
Morphology	1. The science of the forms and structure of organisms. 2. The form and structure of a particular organism, organ, or part. (<i>Dorland's Illustrated Medical Dictionary</i>)
Negative control	two types of negative control exist – negative <i>tissue</i> controls, and negative <i>reagent</i> controls. Non-reactive elements in the patient specimen may serve as a negative tissue control. A negative reagent control is a section of patient tissue cut from the same paraffin block as the patient section to be immunostained. The section is processed in an identical manner to the patient test specimen but with the primary

antibody omitted. A negative reagent control must be performed for each patient test specimen. (*College of American Pathologists*)

Nucleus

1. The central core of a body or object. 2. Cell nucleus: a spheroid body within a eukaryotic cell, separated from the cytoplasm by the nuclear envelope (which is penetrated by pores to allow communication with the cytoplasm), and containing chromatin, a nucleolus or nucleoli, and nucleoplasm. In the nucleus the cell's genetic information is stored on the chromosomes and RNA transcription and processing occur. (*Dorland's Illustrated Medical Dictionary*)

Oncology

the sum of knowledge concerning tumors; the study of tumors. (*Dorland's Illustrated Medical Dictionary*)

Paraffin

a purified mixture of solid hydrocarbons obtained from petroleum, occurring as an odorless, tasteless, colorless or white, more or less translucent mass; used for embedding histological specimens and as a stiffening agent in pharmaceutical preparations. (*Dorland's Illustrated Medical Dictionary*)

Pathology

the study of the nature and cause of disease, which involves changes in structure and function. (*Goudge Report*)

Peroxidase

1. any of a group of enzymes of the oxidoreductase class that catalyze the oxidation of organic substrates by hydrogen peroxide, which is reduced to water [EC 1.11]. These enzymes are heme proteins, found frequently in plants and occasionally in animal tissues. 2. a specific oxidoreductase that catalyzes the reaction of hydrogen peroxide and halide ions to produce cytotoxic acids (such as hypochlorous acid) and other intermediates; these play a role in oxygen-dependent killing of microorganisms and tumor cells. The enzyme is a hemoprotein found in the azurophil granules of neutrophils and the primary lysosomes of monocytes and it has the green color seen in pus. Deficiency of the enzyme, an autosomal recessive or acquired trait, is usually asymptomatic but may predispose affected individuals to severe fungal infections. (*Dorland's Illustrated Medical Dictionary*)

- pH** the symbol relating the hydrogen ion (H⁺) concentration or activity of a solution to that of a given standard solution. Numerically the pH is approximately equal to the negative logarithm of H⁺ concentration expressed in molarity. pH 7 is neutral; above it alkalinity increases and below it acidity increases. (*Dorland's Illustrated Medical Dictionary*)
- Pipette** a glass or transparent plastic tube used in measuring or transferring small quantities of liquid or gas. (*Dorland's Illustrated Medical Dictionary*)
- Positive Control** ideally, tissue that is identical to the patient tissue with respect to fixation, processing and specimen type. For most laboratories, however, it is impractical to maintain separate banks of control tissue for every fixative and specimen type encountered in routine practice. Where control tissues that are fixed and processed identically to the patient specimen are not available, a laboratory may reasonably use its normal control tissues, provided they exhibit equivalent immunoreactivity, which a laboratory validates by parallel testing. Comparable antigen expression confirms the validity of using routine control tissues for specimens that are processed differently. (*College of American Pathologists*)
- Primary** first in order or in time of development; principal. (*Dorland's Illustrated Medical Dictionary*)
- Progesterone** the principal progestational hormone of the body, liberated by the corpus luteum, placenta, and in minute amounts by the adrenal cortex. (*Dorland's Illustrated Medical Dictionary*)
- Prognosis** prognosis - forecast as to the probable outcome of an attack of disease; the prospect as to recovery from a disease as indicated by the nature and symptoms of the case. (*Dorland's Illustrated Medical Dictionary*)
- Protein** any of a group of complex organic compounds which contain carbon, hydrogen, oxygen, nitrogen, and usually sulfur, the characteristic element being nitrogen. Proteins, the principal constituents of the

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protoplasm of all cells, are of high molecular weight and consist essentially of combinations of α -amino acids in peptide linkages. Twenty different amino acids are commonly found in proteins, and each protein has a unique genetically defined amino acid sequence which determines its specific shape and function. Their roles include enzymatic catalysis, transport and storage, coordinated motion, nerve impulse generation and transmission, control of growth and differentiation, immunity, and mechanical support. (*Dorland's Illustrated Medical Dictionary*)

- Quality assurance** a program for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met. (*Medline Dictionary*)
- Quality control** quality control is a system of routine techniques and activities used to control the quality of the product being produced or service being provided.
- Radiology** the branch of medicine concerned with radioactive substances, including X-rays, and the application of this information to prevention, diagnosis, and treatment of disease. (*Dorland's Illustrated Medical Dictionary*)
- Retort** an enclosed chamber that holds the tissue specimens and in which processing occurs"
Exhibit P-3624, p.5 (Tissue-Tek® VIP™ 5 Vacuum Infiltration Processor Operating Manual).
- Scintillation Counter** an instrument for indicating the emission of ionizing particles, making possible the determination of the concentration of radioactive isotopes in the body or other substance; the radiation is absorbed by a specific type of crystal or liquid that subsequently emits minute flashes of light, which are detected and amplified by a photomultiplier tube and counted if they fall within a preset window of energies characteristic of the radioisotope in question. (*Dorland's Illustrated Medical Dictionary*)
- Secondary** second or inferior in order of time, place, or

	importance; derived from or consequent to a primary event or thing. <i>(Dorland's Illustrated Medical Dictionary)</i>
Slide	a glass plate on which objects are placed for microscopic examination. <i>(Dorland's Illustrated Medical Dictionary)</i>
Slurry	a watery mixture of insoluble matter. <i>(Medline Dictionary)</i>
Stain	any dye, reagent, or other material used in producing coloration, such as a substance used in coloring tissues or microorganisms for microscopical study. <i>(Dorland's Illustrated Medical Dictionary)</i>
Stroma	the matrix or supporting tissue of an organ, as distinguished from its parenchyma or functional element. <i>(Dorland's Illustrated Medical Dictionary)</i>
Tamoxifen	an anti-estrogen drug used to treat breast cancer.
Tertiary	third in order. <i>(Dorland's Illustrated Medical Dictionary)</i>
Tissue	an aggregation of similarly specialized cells united in the performance of a particular function. <i>(Dorland's Illustrated Medical Dictionary)</i>
Titer	the quantity of a substance required to produce a reaction with a given volume of another substance, or the amount of one substance required to correspond with a given amount of another substance. <i>(Dorland's Illustrated Medical Dictionary)</i>
Tumour	1. Swelling, one of the cardinal signs of inflammation; morbid enlargement. 2. A new growth of tissue in which the multiplication of cells is uncontrolled and progressive; called also neoplasm. <i>(Dorland's Illustrated Medical Dictionary)</i>
Validate	check or prove the validity or accuracy of: all analytical methods should be validated in respect of accuracy. <i>(Oxford)</i>

Ventana Benchmark® an automated slide processing system that completely automates processing of immunohistochemistry slides (among others) and eliminates over 80% of manual involvement required by other (semi-automated) systems; this machine allows optimization of protocols and the automation of any or all of the slide preparation steps. (*www.ventanamed.com*)

Water bath 1. A conductive or convective medium, as water, vapor, sand, or mud, with which the body is washed or scrubbed or in which the body is wholly or partly immersed for therapeutic or cleansing purposes. 2. The application of a conductive or convective medium to the body for therapeutic or cleansing purposes. 3. A piece of equipment or scientific apparatus in which a body or object may be immersed. (*Dorland's Illustrated Medical Dictionary*)

Xylene a mixture of all three isomeric hydrocarbons, $C_6H_4(CH_3)_2$, from methyl alcohol or coal tar, with uses including solvent and clarifier for microscopy, protective coating, and in various syntheses. (*Dorland's Illustrated Medical Dictionary*)

Acronyms and Abbreviations

ABC	Avidin-biotin Complex
CAP	Canadian Association of Pathologists
CAP	College of American Pathologists
CCHA	Canadian Council on Health Services Accreditation
CEO	Chief Executive Officer
CMA	Canadian Medical Association
CME	Continuing Medical Education
COI	Commission of Inquiry
CPSI	Canadian Patient Safety Institute
DAB	Diaminobenzadine
DCIS	Ductal Carcinoma In-Situ
EDTA	Ethylenediaminetetraacetic Acid
ER	Estrogen
ER/PR	Estrogen Receptor and Progesterone Receptor
FDA	US Food & Drug Administration
FISH	Fluorescence in situ hybridization
H&E	Haematoxylin and Eosin
HCCSJ	Health Care Corporation of St. John's
HCS	Health & Community Services

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Her2/neu	Human Epidermal growth factor Receptor2
HIER	Heat-induced Epitope Retrieval
HIROC	Healthcare Insurance Reciprocal of Canada
HRP	Horseradish Peroxidase
Ig	Immunoglobulin
IHC	Immunohistochemistry
LCIS	Lobular Carcinoma In-Situ
MAC	Medical Advisory Committee
MIS	Management Information Systems
MLA	Medical Laboratory Assistant
MLT	Medical Laboratory Technologist
NEQAS	National External Quality Assessment Scheme (<i>Exhibit P-3631</i>)
NIST	National Institute of Standardized Testing
NLMA	Newfoundland & Labrador Medical Association
NSH	National Society of Histotechnology
OLA	Ontario Lab Accreditation
OPIS	Online Patient Information System
PA	Pathology Assistant
PAP	Peroxidase Anti-peroxidase
PARIS	Prevention, Advocacy, Research, Information and Support
PAS	Periodic Acid-Schiff Stain
PBS	Phosphate Buffered Saline

PIP	Performance Improvement Program
PR	Progesterone
QA	Quality Assurance
QMPLS	Quality Management Program Laboratory Services
SOP	Standard Operating Procedures

